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MEDICARE PRESCRIPTION DRUG BENEFIT

HEARING

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UNITED STATES SENATE

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MEDICARE PRESCRIPTION DRUG BENEFIT

WEDNESDAY, JUNE 23, 1999

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:06 a.m., in room SD–215, Dirksen Senate Office Building, Hon. William V. Roth, Jr., (chairman of the committee) presiding.

Also present: Senators Chafee, Grassley, Hatch, Jeffords, Mack, Moynihan, Baucus, Breaux, Conrad, Graham, Bryan, Kerrey, and Robb.

OPENING STATEMENT OF HON. WILLIAM V. ROTH, JR., A U.S. SENATOR FROM DELAWARE, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will please be in order.

Today the committee will explore considerations for adding a prescription drug benefit to the Medicare program. The absence of a prescription drug benefit has been of concern since the program was enacted in 1965. Currently, Medicare covers only a limited number of pharmaceuticals: those provided in inpatient care, immunosuppressive and anticancer drugs, as well as specific immunizations.

Approximately 35 percent of the 39 million Medicare beneficiaries have no prescription drug coverage, although a portion of these beneficiaries may be unaware of their Medicaid eligibility.

The remaining 65 percent of Medicare beneficiaries rely on Medigap, private supplemental coverage, Medicare+Choice plans, Medicaid, or employer-sponsored plans for their prescription drug coverage. However, drug benefits and out-of-pocket costs vary widely for beneficiaries in these various programs.

The most recent data indicates that the average drug expenditures for care per beneficiaries are roughly $600 per year, and half of these costs are paid out of pocket by the beneficiary.

However, these averages conceal wide variations in spending. I am particularly concerned about low-income beneficiaries and the sickest beneficiaries who have very high annual expenses.

Today, the committee will hear important testimony that will address a number of design, coverage, and cost issues for consideration in the development of a prescription drug benefit.

Finally, I must mention that recent estimates indicate a $1 trillion infusion of new money will be required simply to sustain the existing Part A benefits through the year 2027, and a drug benefit

alone could easily cost $300 billion over the next 10 years. So, I want my colleagues to fully understand how daunting this challenge is.

Senator Moynihan?

OPENING STATEMENT OF HON. DANIEL PATRICK MOYNIHAN, A U.S. SENATOR FROM NEW YORK

Senator MOYNIHAN. Thank you, Mr. Chairman. Daunting, but in every way attractive. We are not dealing with a bad problem here, we are dealing with a good development, which is the emergence of new pharmaceuticals in the manner of medical science in our age that has enormous benefits, and costs.

The costs are not always in the direction you think. The development of Zantac and that family of antacid medications has reduced the number of operations for ulcers in American hospitals by three-quarters in 10 years. It is going away.

It has also been hugely embarrassing to three generations of psychologists who explained that you have an ulcerous personality, when, in fact, no, you did not, you just had excess acid, which one little pill could make go away.

We should welcome this as a regular sequence in the development of health care and ask ourselves how much we can afford, and see if we cannot find the resources, therefore.

So, thank you for this hearing, and let us go.

The CHAIRMAN. Thank you, Senator Moynihan.

I am going to ask all other members to submit their testimony, as we have a very, very full day. I would also ask our witnesses, as well as our members, to keep within the time limits, because we do have so many witnesses.

I think it is such a promising, important matter, we want to hear from all of them. So, written questions will be permitted until 7:00 this evening. Of course, the full statements of all of the witnesses will be included as if read.

So, with that, it is my great pleasure to welcome our first panel of experts. Each of these witnesses bring a particular expertise on the question of prescription drug benefits.

We are very pleased to hear from Ms. Laura A. Dummit of the General Accounting Office; Dr. Michael Gluck, of the National Academy of Social Insurance; and Mr. Kevin Concannon, the commissioner of the State of Maine Department of Human Services.

We are delighted to have you. Ms. Dummit, we will start with you, please.

STATEMENT OF LAURA A. DUMMIT, ASSOCIATE DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH ISSUES, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, GENERAL ACCOUNTING OFFICE, WASHINGTON, DC

Ms. DUMMIT. Thank you, Mr. Chairman and members of the committee. I am pleased to be here today as you consider the potential for a prescription drug benefit for Medicare beneficiaries.

In your hearings on Medicare reforms to modernize the program and control its impact on the Federal budget, one of the most significant issues to emerge has been whether or not to add prescription drug coverage.

Prescription drug expenditures have been outpacing other components of health care spending in recent years due to a variety of factors, including the introduction of new drug therapies and improved drugs, a rise in the number of individuals with third party drug coverage, and more aggressive marketing of drugs directly to consumers.

The much higher incidence of chronic conditions and the accompanying role drugs play in managing such conditions among the elderly means that they are particularly affected by this spending growth. One-third of Medicare beneficiaries do not have prescription drug coverage and face the cost of drugs on their own.

They lack coverage either because they are not eligible for employer-sponsored benefits of Medicaid, they cannot or do not choose to enroll in a Medicare+Choice plan, or cannot afford or do not purchase a Medigap policy with this protection.

Even for those with such a benefit, however, coverage is often limited and may involve substantial cost sharing. These limitations in coverage can have a substantial impact on seniors, particularly those with serious health conditions.

This is the context within which proposals for including a prescription drug benefit in the Medicare program will be discussed. Assessing the merits of whether, and how, to implement a Medicare drug benefit will include a number of factors, especially who the benefit will cover and how it would be financed. The Congress will also likely examine a number of alternative design and administration options to keep spending under control.

I would like to briefly discuss two of the approaches that may be considered. One approach would model the implementation of a Medicare drug benefit after the Medicaid rebate program, which requires drug manufacturers to give State Medicaid programs rebates for outpatient drugs based on the lowest or best price they charged other purchasers. Given the share of drug utilization accounted for by the Medicare beneficiaries, such an approach could substantially affect the pharmaceutical market.

Concerns also exist about how much of a discount from prior prices the rebates have represented, and the lack of control over utilization which, unchecked, can contribute significantly to spending.

Other payors, including private insurers and Medicare+Choice plans, have taken a different approach to managing their drug benefits by attempting to control and channel drug utilization through the use of formularies and cost sharing.

These mechanisms not only contribute to controlling use, but they allow payors to concentrate purchases on selected drugs and thereby obtain significant discounts for manufacturers.

These techniques are changing the market from one in which insured individuals purchase drugs at retail pharmacies at retail prices and then seek reimbursement to one in which third party payors influence which drug is purchased, how much is paid for it, and where it is purchased.

Adopting some of these techniques for Medicare might help to control costs. However, how to adapt these techniques to deal with the unique characteristics and enormity of the Medicare program raises many questions.

Taking full advantage of negotiated or competitively determined prices would require restricting Medicare coverage to a formulary or imposing differential beneficiary cost sharing on different drugs.

The financial implication of including particular drugs on a Medicare formulary or providing them with preferential treatment with respect to cost sharing could be enormous. Such decisions, which plans or insurers make privately, would have to be made publicly for Medicare.

Assembling sufficient, valid, and defensible information to guide formulary choices would be daunting. Delegating this and other benefit administration tasks to a pharmacy benefit manager may also prove difficult. A single PBM contractor would have no more flexibility than Medicare to employ the techniques it uses for private payors to generate savings.

Contracting with multiple PBMs raise other issues. If each had exclusive responsibility for a geographic area, beneficiaries needing certain drugs may be advantaged or disadvantaged merely because of where they live.

Allowing beneficiaries to choose among competing PBMs would raise issues about informing beneficiary choices and risk adjusting PBM payments for differences in enrollee health status.

In conclusion, adding prescription drug coverage to Medicare would have a substantial impact on the costs of the program, in addition to the financial well-being and health of many of its beneficiaries.

The challenge will be in designing and implementing a drug coverage to minimize the financial implications for Medicare, while maximizing the positive effect of such coverage on Medicare beneficiaries.

Mr. Chairman, that concludes my remarks, and I would be glad to answer any questions you or other members may have.

[The prepared statement of Ms. Dummit appears in the appendix.]

The CHAIRMAN. Thank you, Ms. Dummit.

Dr. Gluck, who is director of Health Policy Studies, National Academy of Social Insurance. Welcome.

STATEMENT OF MICHAEL GLUCK, PH.D., DIRECTOR OF HEALTH POLICY STUDIES, NATIONAL ACADEMY OF SOCIAL INSURANCE, WASHINGTON, DC

Dr. GLUCK. Thank you, Chairman Roth, Senator Moynihan, and members of the committee. Thank you for inviting me to appear before you today.

The National Academy of Social Insurance is a nonprofit, nonpartisan research and education organization. Among our activities, we convene carefully balanced committees of experts to wrestle with policy issues regarding the future of Social Security, Medicare, and other social insurance programs.

For the past 4 years, about sixty such experts have come together, in five separate committees, to work on Medicare's long-term future.

At a time when we are trying to decide how we will finance Medicare's current benefits, the most salient questions about poten-

tial new drug coverage are: do we need it, and how much would it cost?

With a few exceptions, Medicare does not pay for drugs used outside of the hospital. However, pharmaceutical therapies have become increasingly important as a direct result of our investments in biomedical research. The pace of these scientific advances is accelerating.

Because of these new, exciting therapies, spending on pharmaceuticals has been rising faster than other components of the health care bill. Our analysis indicates that, in 1999, spending on outpatient pharmaceuticals would average about $940 per beneficiary, roughly half paid by insurers and half paid out of pocket by beneficiaries. These expenditures are skewed.

A large fraction of beneficiaries spend relatively little on drugs, but a minority spend a great deal. About half of beneficiaries have out-of-pocket drug expenditures of less than $200 a year, but 14 percent have out-of-pocket of $1,000 or more, and 4 percent have expenses that exceed $2,000.

According to a recent estimate, about 65 percent of Medicare beneficiaries had some form of prescription coverage in 1995. Nonetheless, there are reasons to be concerned about the adequacy of protection this coverage affords. Not all coverage is equal. Supplemental policies vary a lot in what they pay for drugs.

In addition, the protection against the high cost of drugs offered by supplemental policies may be eroding over time. Employer-sponsored coverage is being offered to fewer retirees and, when offered, it is significantly more limited than in the past. Medicare+Choice plans are also placing more limits on their pharmaceutical coverage, or they are increasing premiums to beneficiaries, or both.

Third, the cost of individual Medigap policies that offer prescription drug coverage is prohibitively expensive for many beneficiaries, and increasing. This drug coverage, which is not particularly generous, often has costs that exceed the maximum benefit it provides.

What about the 35 percent of Medicare beneficiaries who have no drug coverage? We know that poor and near-poor beneficiaries are more than twice as likely as non-poor beneficiaries to have no supplemental coverage beyond Medicare. Because they lack prescription drug coverage and have fewer resources to pay out of pocket, they are particularly vulnerable should they incur substantial pharmaceutical costs.

To look at how much a prescription drug benefit would cost, we commissioned actuaries to estimate the cost of five drug benefits that are similar to many policies found in the private sector. This coverage would add about $18-24 billion to Medicare costs in 1999. This represents 7 to 13 percent of existing Medicare costs.

We also found that the cost of so-called stop loss coverage rises substantially over time. Stop loss coverage protects beneficiaries by paying all of their drug costs once they incur a certain amount of out-of-pocket expense.

Among other questions for policy makers considering Medicare drug coverage are: would the drug benefit cover all beneficiaries, or only those with extremely high drug expenses, or only low-income beneficiaries who did not qualify for Medicaid?

How would we finance a benefit? Would we expect employers in States who currently help pay for drugs for some Medicare beneficiaries to contribute towards the cost of a Medicare benefit?

Would we provide subsidies to help lower income beneficiaries pay any premiums, deductibles, and co-payments? Who would administer the benefit, and how? Would we allow formularies? And, perhaps most controversially of all, how much would Medicare pay for each drug?

The overriding question is, should we use social insurance to spread the risk of prescription drug expenses? Do we want to integrate drugs into the Medicare benefits package to provide equal coverage to all beneficiaries, or do we want to seek new ways to integrate public, employer, and individual responsibility for covering these costs?

That concludes my remarks, and I will be happy to answer your questions.

[The prepared statement of Dr. Gluck appears in the appendix.]

The CHAIRMAN. Thank you, Dr. Gluck.

Now it is my pleasure to call on Mr. Concannon.

STATEMENT OF KEVIN W. CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AUGUSTA, ME

Mr. CONCANNON. Thank you, Mr. Chairman, Senator Moynihan, members of the committee. My name is Kevin Concannon and I am the commissioner of the Department of Human Services in the State of Maine.

I am genuinely pleased to be here before the committee today, especially because of the subject that you have at hand. As a State official now in Maine, but for a number of years in Oregon, I, our department, our office, receives daily inquiries, pleas, from residents of our State struggling with the cost of drugs and pharmaceuticals.

Maine is one of 15 States in the country to have not only a Medicare program for low-income, and increasing, as I think the committee is aware, for middle income people, but we have a Drugs for the Elderly program that covers people whose incomes are above the Medicaid limits, and I will speak to that momentarily.

But, first, a little bit of background about Maine. It is a State of 1.2 million people. On any given day, the Medicaid program covers 164,000 insured lives. Over the course of the year, that is 200,000 people.

In dollars, the Maine Medicaid program is $1.2 billion per year, of which $140 million represents the drug benefit. I cannot underscore how important and efficacious that drug benefit is.

As the committee members are aware, drug benefits under Medicaid are optional, but virtually all States in the country avail themselves of that because of the efficacy and the urgency in the need for drug benefits.

In Maine, some 57,000 Maine residents, elderly and disabled persons, depend for their drug benefit either on our Medicaid program or on our Drugs for the Elderly program.

We use a point-of-sale information technology system to really track the cost, to track information, eligibility, utilization, a number of factors associated with that Medicaid program.

But I must point out to the committee something that I am sure you are aware of. In our State, and virtually all of the States in the country, State Medicaid programs are struggling with double-digit increases in the cost of drugs annually.

It is the fastest rising part of the medical market basket. We have been able to control costs in health care and other areas, but this is a virtual double-digit increase each year. That increase is associated with new drugs coming on line that are invariably more costly.

The increasing cost of generic drugs, the direct marketing to consumers by the drug manufacturing companies, and the manufacturer of look-alike, or what we call "me too" drugs that have the effect of extending the patent on individual drugs, which in the past those patents may have run out, therefore making drugs more affordable to consumers.

The Medicaid program in our State contains costs by relying on cost caps, the drug rebate program which I will speak to momentarily, the monitoring of our point-of-sale information systems, the use of prior authorization, express preference for generics over name-brand drugs, and our developing an increasing focus on drug prescribing practices by physicians.

Now, let me turn to the Drugs for the Elderly program in our State. Maine, for some 20 years, has had a growing Drugs for the Elderly program. Currently, it provides benefits for elderly and disabled persons whose incomes fall below 134 percent of poverty. That is roughly $11,000 per year for a single person. We are one of 15 States that have similar programs that vary somewhat in scope.

With the action of our most recently ended legislature this past Friday, Democrats, Republicans, and our independent Governor, we agreed to increase that program to cover people up to 185 percent of poverty.

We cover people in that program for roughly 12 conditions. I will not highlight all of them, but they are for conditions that affect the elderly: diabetes, cardiac conditions, obstructive lung disease, incontinence, high blood pressure, et cetera.

We cover drugs that treat these conditions. The consumer pays 20 percent of the Medicaid cost. I think this is a very important element in our program. Maine, like virtually all Medicaid programs in the country, does not pay what I call the sticker price on drugs. We pay a discount. It is an average wholesale price, minus 10 percent.

Then we have agreements with all of the drug companies where we secure a rebate. That has the effect of actually, in the aggregate, or netting, I should say, reducing the cost of that drug by roughly 35 percent. We rely upon that rebate program to help finance our Medicaid program, but we also rely upon it for the Drugs for the Elderly program.

We are mindful of the fact that our Senator, Senator Snowe, and Congressman Tom Allen in the southern part of Maine, each have introduced legislation this session as well.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Concannon appears in the appendix.]

The CHAIRMAN. Thank you.

I would announce again to members of the panel that we are going to very strictly apply the time limits today because we have so many here, and we want to ensure that all of the witnesses has a chance to present their testimonies.

Ms. Dummit, in order to improve drug coverage for Medicare beneficiaries, where do you think we should focus our initial efforts? We know that drug benefits can be costly, so where can we do the most good initially?

Ms. DUMMIT. Well, as you and others have said, and I will reiterate, this could be a very expensive proposition for the Medicare program, but again very valuable for its beneficiaries.

I think that if you were discussing a more targeted approach, it might be appropriate to draw from the Breaux-Thomas proposal and focus those efforts on those beneficiaries who do not qualify for Medicaid, yet do not have incomes that allow them to either purchase the Medigap policies or to pay for these drugs out of pocket.

There are certain categories of beneficiaries where the lack of prescription drug coverage has a disproportionate effect. So, it would be those near-poor who cannot qualify for Medicaid.

The CHAIRMAN. Let me ask you, Dr. Gluck. Would you expand on your discussion of the trade-offs involved in having a drug benefit that has a maximum government payment versus a drug benefit that protects beneficiaries from catastrophic drug expenses?

What, in your judgment, would be a drug spending level that would balance fiscal responsibility with the basic desire of ours to provide truly valuable coverage to the sickest beneficiaries?

Dr. GLUCK. Senator, the catastrophic coverage that you mentioned affords the greatest protection over time for beneficiaries against the high risk of drug bills. It specifically helps those folks with extraordinary expenses.

However, this type of benefit becomes very expensive over time. This is because we expect drug spending in the United States to continue to grow faster than general inflation than the economy or other Medicare services. So even if you indexed the catastrophic amount to inflation or Medicare growth, its costs would still continue to grow.

A benefit with a maximum protection, which is what the Medigap policies have now in an increasing number of managed care plans, has relatively stable costs over time because the government, in effect, is decided a priori how much it wants to spend.

But, in limiting the Federal exposure, that benefit would place the risk of high drug costs back on the beneficiary. Again, that risk becomes greater over time as drug spending increases in the economy as a whole.

As to your second question about what would be fair, the National Academy of Social Insurance does not take positions on policy issues.

I can tell you, if you look at the five benefits that we estimated and ranked from lowest to highest cost, the one that would fall in the middle would have a $200 deductible, would require beneficiaries to pay 50 percent of the cost of the drug, and have a $2,000 catastrophic limit. But all we have is the analysis that we did.

The CHAIRMAN. Let me ask you, Mr. Concannon. Do you think Medicare should try to build on the Medicaid pharmaceutical programs or the State-only drug assistance programs?

Mr. CONCANNON. Mr. Chairman, that is a tough question. It is going to vary State to State. In the case of Maine, I think that is an option that we might welcome because we already operate a Drugs for the Elderly program. We rely upon the technology of Medicaid, but it is separately administered and the eligibility is overseen by our State Treasury Department.

I think what I would say, is States would like options in this regard. But I think, for me, one of the most important concerns, as the Congress considers this benefit, would be to provide more flexibility, whether it is administered by the States either in a Medicaid-type program, or a separate Drugs for the Elderly, to have more flexibility both in terms of which drugs they are required to reimburse for.

I am mindful of the concerns expressed by States about lifestyle enhancing drugs that are costly, that it seems questionable to us whether we ought to be spending public funds in that regard.

Yet, we feel at the State level right now we do not have enough tools, in terms of discretionary tools, to be able to limit the payment of public funds to those drugs that are truly efficacious for people.

The CHAIRMAN. Senator Moynihan?

Senator MOYNIHAN. Mr. Chairman, I have just a general question for the panel, and this was fine testimony. Are we witnessing a transformation of medicine in the aftermath of so many new drugs? I mean, the increased share of medical costs involved with prescription drugs is mostly due to increased volume.

We continually hear of hospitals with empty beds, which denotes a change in medicine. Beds used to be where you went to die, in hygienic circumstances, before there was any real treatment.

How do you feel about that? Should we not look upon this as that medicine is changing, not that we are adding a benefit to the programs that we recently had?

Mr. CONCANNON. Certainly, our experience, I would say, at the State level, we expend about $140 million now in drug benefits. We expend just over $40 million in physician payments.

If you were to look back 15 years ago, we would have spent more on physician payments than on drug benefits. Our experience in that regard, I think, is very similar in other parts of the country, that drug benefits are surpassing what we are paying to physicians.

Senator MOYNIHAN. And with an appropriate measure of efficacy.

Mr. CONCANNON. Very much so. Maine is a State, for example, as is true of a number of States, in which the number of residents in long-term care or nursing facilities is down now, even at a time when we have an aging population.

One of those factors, certainly, is the benefit, the efficacy of certain medications that allow people to enjoy a quality of life outside of an institutional setting.

Senator MOYNIHAN. Dr. Gluck, is that your sense?

Dr. GLUCK. In 1965, when Medicare was put in place, there was very little that pharmaceuticals could do relative to what they can

do now. My reading of the record is, that is why they were not included in the benefit package then.

Senator MOYNIHAN. That is right. The science had not arrived. The most important thing they could do, they had been outlawed. I have just received a copy of the 1899 Merck Manual that describes the fine products available from the Merck company, and it includes cocaine hydrochlorite. "Merck's cocaine strictly conforms to the U.S.P. in all of the known tests for its purity." [Laughter.] We have to be a little careful.

But you would agree with Mr. Concannon?

Dr. GLUCK. It is hard to predict the future, but we do know we are investing a great deal in biomedical research now. Indications are that the pace of discovery is accelerating. It could be within a few decades that much of what is done in the hospital may be treated through pharmaceuticals. We do not know, but that seems to be the trend.

Senator MOYNIHAN. We are not adding to a hospital program. Maybe we will be dealing with a change in medicine in which hospitals begin to recede as the mode of treatment.

Ms. Dummit?

Ms. DUMMIT. I think that there is certainly a lot of evidence to back up what you are saying in terms of very large changes in medical practice, not only in terms of prescription drug coverage, but related to that, the tremendous increase we have seen in outpatient surgeries, as well as in-home health care. Largely, because of pharmaceutical advances, we can do a lot of procedures now in less intensive settings.

Senator MOYNIHAN. Thank you.

Mr. Concannon, could you give us, when you have a moment, those numbers on medical residents in Maine as against the pharmaceutical rise and the concomitant decline?

Mr. CONCANNON. Certainly. I would be happy to.

Senator MOYNIHAN. Thank you. Thank you all very much.

The CHAIRMAN. Senator Baucus, please.

Senator BAUCUS. Thank you, Mr. Chairman.

I think this is an interesting point that we are now developing, and I think it is accurate. It relates to how much our economy is changing, the world economy is changing, through advances in technologies of all sorts, including the communications technology, which is radically changing how we do business, and questioning whether laws can catch up with what is happening in the world. We will always be behind, but it seems to me we run the risk of laws being further behind because technology, including new drugs, is changing so quickly.

My question is, given all that, what do we do? That is, it seems to me, as we approach prescription drugs, one question is, would we target the 65 percent, or the 35 percent, or everybody? The 100 percent or the 35 percent?

Another question is, is it just an add-on or do we restructure Medicare in some way? The third question is, without harming R&D, how do we get some control over the increased cost of drugs? As we all know, drugs are increasing at a rate faster than other health care components. I think 15 percent annually, is what I

heard. That might be a bit off. The elderly do complain, legitimately, about the cost of drugs.

So as we move forward and science encourages this new trend we are talking about, where pharmaceuticals are a greater proportion than, say, doctors' fees, improving the quality of life of people but at quite an expense, and ultimately where maybe fewer people get the very best care because they get the very best technology compared with some others, including drugs, perhaps, what do we do? How do we structure this thing, who do we cover, and without sacrificing R&D, how do we get a handle on the costs?

As someone made famous a long time ago, there is no free lunch here. We have got to make choices. I would just like your guidance as to how we make those choices and how we deal with this. Beginning with you, Ms. Dummit.

Ms. DUMMIT. Well, I think that you have certainly laid out some of the major dimensions that are going to affect the cost of any kind of a prescription drug benefit. Certainly, who is covered, and how much they are covered for are two of the basic design issues.

Senator BAUCUS. And what do you think?

Ms. DUMMIT. Those are hard, hard choices.

Senator BAUCUS. That is why I am asking you. [Laughter.]

Ms. DUMMIT. There really is no easy answer when you are dealing with the Medicare population because, as you said, two-thirds of beneficiaries have some form of coverage. How adequate that is, is open to question for at least some of them who, without coverage, are feeling the full impact of the rising costs of pharmaceuticals.

Another way to limit or scope the benefit has to do with how much cost sharing you impose on Medicare beneficiaries and what kind of a limit.

Senator BAUCUS. We know some of the options here. I am just trying to get your sense of what we do, what suggestions you have as to how we solve that.

Ms. DUMMIT. One approach, would be to focus on those beneficiaries who cannot qualify for Medicaid because of their income, yet cannot afford to purchase coverage.

Senator BAUCUS. I do not have much time here. Thank you.

Dr. Gluck, your thoughts?

Dr. GLUCK. Well, this may be a case, Senator, where the technology in medicine is outstripping the technology that we have available to manage a potential benefit. We do have some good models out there from the States, as we have heard, and also from the private sector. But to take one example, some of the legislation for prescription drug benefit that has been introduced already would rely on competitive purchasing of drugs.

This is an area, in general, which a lot of people believe holds a lot of promise, but as examples the demonstrations where we have tried to use competitive purchasing in other parts of the Medicare program have shown——

Senator BAUCUS. I see a yellow light there. I want to try to get to Mr. Concannon.

Dr. GLUCK. All right. It may be an area where we want to invest in additional research.

Senator BAUCUS. Thank you.

Mr. CONCANNON. Senator, I would sign up for the strategy that has been employed by the 50 States in their Medicaid program, and that is, not paying the average wholesale price or the sticker price. I find that sort of comparable to Avis or Hertz sort of paying the sticker price when they buy from General Motors.

Senator BAUCUS. Could you explain your rebate program? That was interesting.

Mr. CONCANNON. The rebate program. Virtually all States participate in this. Because we are large purchases with the drug companies, we require the drug companies to give back to the States the same discount that they give to the largest private purchasers.

That way, that has the effect, in the aggregate, of reducing the cost to the States at roughly 30 percent. If you take the same and extend it over into Medicare, you would have some way of containing the cost, and then have a progressive cost sharing as a person's income went up.

Senator BAUCUS. All right. Thank you very much.

The CHAIRMAN. Senator Graham, please.

Senator GRAHAM. Thank you, Mr. Chairman.

Before I turn to some questions, I would comment that it seems to me it is important in this debate on Medicare reform that we, first, focus on what is the set of benefits that we want to make available to the Medicare population, and then the question of how to finance that benefit.

We know that today the average Medicare beneficiary is paying about as much out of pocket every year for their Medicare benefits as the Federal Government is contributing.

So, there are a lot of resources on the table between the Federal Government and the beneficiaries, the question is how to most intelligently organize those resources.

The issue of prescription drugs, to me, is a little bit like the issue of anesthesiology. It used to be that anesthesiology was not a customary part of medical procedures, which made medical procedures pretty painful. The idea today of having anesthesiology not as an integrative part of a modern medical set of benefits would be considered to be virtually inhumane.

I would suggest that we are at the point of reaching the same judgment relative to some of the major omissions from Medicare, of which prescription medication is maybe the most obvious, that it would be not only bad medicine, but inhumane not to make available, as part of the Medicare program, something which is as common in virtually every other medical financing program and is as expected by the beneficiaries as it access to the modern miracles of pharmacology.

It seems to me that, with that background, in terms of how to pay for it, one of the questions is, how do we pay for this in a joint Federal Government/beneficiary manner that does not result in adverse selection? That is, only those who are the most in need being those who access the programs.

Theoretically, Part B of Medicare is a voluntary program. Nobody is required to pay the Part B premiums unless they elect to do so. The fact is, it is structured in a way that is so attractive that it has virtually universal acceptance and, therefore, coverage.

That is a 75/25 program. That is, the Federal Government pays 75 percent, the beneficiary 25 percent. If you were to make prescription drugs as a second election, that is, after you had elected Part B, then you could make a second election for prescription drugs, what do you think the relative share, 75/25 or some other percentage, would be required in order to get the same level of universality of coverage that we have in the basic Part B program?

Dr. GLUCK. It would depend on the type of benefit that was provided.

Senator GRAHAM. Have you done some analysis of, for instance, what kind of benefit package, at a 50/50 cost sharing, would it take in order to get close to universal acceptance and, therefore, avoid adverse selection?

Dr. GLUCK. That analysis, we did not do. We assumed that all beneficiaries would elect to take the coverage.

Senator GRAHAM. I wonder, could you do some analysis of that?

Dr. GLUCK. We can get back to you.

Senator GRAHAM. There is also what I would refer to as some hydraulics here. That is, as one program changes, it affects other programs. Three of the changes that will be effective in prescription medication, would be in the Medicaid program.

Today, the States, as you have indicated, are paying a substantial amount in order to cover prescription medication that are not covered under Medicare for those who are dual eligibles. So a greater Federal effort in prescription medication would reduce State costs.

There also is the interplay of the Medigap program. About 13 or 14 percent of people are paying out of pocket for prescription medication benefits. So if it were covered in the program, it would have that effect.

Then post-employment benefits. I get a $50 a month benefit from the State of Florida as a State retiree, once I get to be 65, towards my Medigap policy. Assumedly, the State might be willing to devote the same $50 a month towards a prescription medication benefit.

Has anybody analyzed the interplay between a prescription medication benefit through Medicare and its effect on at least those three areas?

Ms. DUMMIT. We have not done any analysis of the relationships among those different payors and a new Medicare coverage. But certainly if Medicare were to implement a universal drug benefit of some sort, it would be substituting dollars that are coming through the private sector or out of pocket for Medigap insurance or other kinds of coverage. So, there is going to be that kind of trade-off among all of those factors that you mentioned.

Senator GRAHAM. Well, let me ask a question.

The CHAIRMAN. Your time is up.

Senator GRAHAM. If Dr. Gluck would take the homework assignment relative to adverse selection, Ms. Dummit, would you take the homework assignment as to hydraulics between Medicare and these other programs?

Ms. DUMMIT. Yes, sir.

Senator GRAHAM. And I think that would contribute to our ability to think seriously about how to structure a Medicare benefit for prescription drugs.

Ms. DUMMIT. Yes, sir.

Senator GRAHAM. Thank you.

The CHAIRMAN. Senator Kerrey?

Senator KERREY. Thank you, Mr. Chairman. Thank you for this excellent panel as well.

Mr. Concannon, I am going to direct my 5 minutes' worth of questioning to you, with great respect to the other witnesses. I appreciate theirs, as well. But I am impressed with the practical side that you have acquired in Maine.

I, like you, receive daily contact and communication from not just seniors, but non-seniors as well, about the cost of prescription drugs. I declare to you, one of the concerns that I have is that, as with any social insurance, I pay for that social insurance with taxes.

We say the government pays for it, but it is really taxes. Right now, the Federal Government is collecting about 20.5 percent of total U.S. income. It is the highest level since 1945. So, we do not have a lot of room to move here. We are consuming a larger share of that 20.5 for transfer payments of all kinds to people over the age of 65 who are going to be demanding more as the baby boomers come out. So, we have got that fundamental problem we have got to address.

One of the problems that I have got, is that if I extend a new tax subsidy, the source of the tax comes from people who are in the work force. Some of those are seniors who are still working, but there are at least 20 million people in the work force without health insurance, taxing them to pay for a benefit to subsidize somebody else.

We know today that there is a direct correlation between the existence of health insurance and health. So I have people out there without health insurance who are not healthy. They probably work at least one job, maybe two jobs, so they do not have time to call me up and express their concerns about problems that they are having, and they are not very well organized, so their concerns do not get very equally expressed in the U.S. Congress.

So, I declare that concern up front. If I am going to tax them to pay for somebody else's benefit, it seems to me that I ought to at least occasionally express some concern for the quality of their life that is deteriorating as a result of the lack of health insurance. With the growing economy, I am disturbed that we have got a growing number of uninsured. I know you have had experience in Maine about that.

You have had some very impressive success on cost controls, especially living close to Canada. You say you have reduced, through six different techniques, you said, cost caps, drug rebates, prior authorization, point of sale, drug prescription practice, generic preferences, by 35 percent the normal retail price.

How does that compare still to the cost of drugs in Canada?

Mr. CONCANNON. Canada. Actually, it is interesting, Senator, that you asked that, because I actually had our staff examine last spring whether we might be able to legally import drugs from New

Brunswick or Quebec because they are less costly. The same drugs by the same manufacturers cost less in the Canadian provinces near us, and that is beyond the differential and the value of the dollar.

Senator KERREY. Why is that?

Mr. CONCANNON. That has to do with patent laws and how long the patents stay in effect in the U.S. compared to in Canada, I have been advised by our folks. But I abandoned that strategy. I am told that Minnesota spent time looking at that same thing, and both of us came to the conclusion that it was too complicated, with FTA issues and others.

But to your question, if I might say, we are using point of sale technology, new information technology that, frankly, has been heavily financed by the Federal Government for a Medicaid program that allows us to track virtually, in real time, the purchase of drugs. We can intercept, we can pick up drug interactions.

Senator KERREY. Do you get privacy problems, Mr. Concannon, with that?

Mr. CONCANNON. No, we do not. We do not because it is limited to the Medicaid program. We are paying for it. We do not share it with other people. But we can go into the files and see, for example, if it is a heavy psychiatric drug, whether they have actually picked the drug up.

What I was going to say is, one of the things we are just developing and have been in the last year is using that information technology with medical consultants in our department. We are examining ways to reward physicians for good prescribing practices.

For example, already we give added bonuses to physicians who show more than 90 percent of their young children patients fully immunized. We say, let us give them a bonus. We are taking that same concept to say, why would we not do that same thing with physicians who show good prescribing practices?

Senator KERREY. Mr. Concannon, let us say we pass a general drug benefit, subsidized at the Part B level, for all 37 million Medicare beneficiaries. Are you concerned that we will then be subsidizing non-essential medicine, given the amount of direct marketing that is going on right now?

Do you think you are going to get an increase in the number of people who will be using tax resources to buy things that will make it difficult for us to do other things that need to be done with social insurance?

Mr. CONCANNON. I would certainly want more flexibility than States currently have to be able to limit the drugs that we pay for. For example, my physician consultant, pharmacy consultant, said, why should we pay $450 for a toenail fungus treatment for somebody out of public funds when we have an elder person who is just above that income level who is getting nothing and needs help with obstructive lung disease or something much more serious.

Senator KERREY. Or cancer. Yes.

Mr. CONCANNON. So I think anything that Congress does needs to have embedded in it, I believe, more ability to make discretionary choices based on science and efficacy, not just paying for everything.

Senator KERREY. Thank you.

The CHAIRMAN. Senator Mack, please.

Senator MACK. I want to pick up on something that Senator Moynihan said, because it really has affected my thinking about this issue. Most of us, I think, have a natural tension between the cost and the need. If you think about it from the way that medicine was delivered in the past, then you really do not understand the new dynamics that are taking place.

I mean, when I came to the Senate, in the area of cancer treatment, for example, you typically heard people talk about surgery, chemotherapy, or radiation. But today you hear terms like immunotherapy and gene therapy.

So what that is saying is, in fact, the delivery of medicine has dramatically changed. I suspect, if we look back 10 years from now, the changes that we will experience in these 10 years will make the past 10 years look like something that was insignificant.

So we are faced with this issue then about how to, in essence, modernize the Medicare program. But, just listening to what has been said here this morning, the cost of this is tremendous.

The plan that you talked about, I think, would be around $18 billion a year. It was a $200 deductible, 50 percent co-insurance, $2,000 stop pay, cost per beneficiary, $463, total cost, $18.3 billion. There is one that is slightly less expensive than that, but that is an enormous amount of money.

We have an incredibly difficult task ahead of us, but I think it is one we have to address. Clearly, there is a change in the way that medicine is being delivered and we have got to both understand it, and I think accept it. So, I am just going to ask one question, and the three of you, whoever wants to hop in, can do so.

Ms. Dummit, you mentioned that there were two approaches. One, is obtaining price discounts from drug manufacturers, the second one—I know I am over-simplifying—is negotiating price discounts from manufacturers. But you laid out limitations to both of those.

I guess my question would be, there have got to be some folks who have been engaged in this process already. Who has been managing pharmacy risks, how have they done it, and what have we learned from their experiences? What are the things that we should do and what are the things that we should not do? Again, I think maybe all three of you have some thoughts about it.

Ms. DUMMIT. Well, certainly private insurers and managed care plans that have a prescription drug benefit as part of their coverage have been dealing with the issue of rising pharmaceutical prices. And as I stated in the testimony, many of them have employed a variety of techniques to try to get those costs under control.

Some of the most prominent techniques involve the use of formularies and they use beneficiary cost sharing, sort of combining those techniques. What these insurers have managed to do is, through the formulary and co-pay, is steer their enrollees to use the least expensive or most efficacious drug in a particular class. By focusing their market share within a particular class of equivalent drugs, they can then use that market share to exact greater discounts from manufacturers.

So these are combined techniques that are trying to control both the price and the utilization of prescription drugs. Those are certainly techniques that could be considered for the Medicare program. However, adopting them wholesale on the Medicare program, simply because of the sheer size—Medicare beneficiaries use a very substantial share of pharmaceuticals in this country—of this program, adapting those techniques for Medicare will obviously be difficult and require careful consideration.

Senator MACK. Anyone else?

Mr. CONCANNON. I would simply add, again, that many of the States have their own pharmacy benefit managers. In our case, we use that information technology to track prescriptions and to continue to communicate with physicians. We send 1,000 a month in our State to physicians, advising them of what we discern in their prescribing practices with patients.

But I would also mention that drug rebate. I think, just as drugs have efficacy for individual patients, it has financial efficacy in terms of large purchasing. I think if there is any consideration to expand the coverage under a program like this, there ought to be some commensurate, in my view, discounting.

Dr. GLUCK. It is my understanding that pharmacy benefit managers often use their relationships with pharmacies to help control costs, too. But I am not the expert on that topic.

The CHAIRMAN. Senator Grassley?

Senator GRASSLEY. Before I ask a question of Dr. Gluck, let me state where I am coming from in this general proposition of prescription drugs.

It seems evident from testimony that we have heard over the last few months and a lot of individual efforts of individual Senators that prescription drugs have obviously become a very integral part of health care delivery. Consequently, we find that the Medicare program is way behind the times in the practice of medicine today.

The dilemma that we face in Congress is what to do about this program, not just in the next few years, but obviously when the baby boomers start to retire it is a very major problem. I want to see Medicare reformed, and for prescription drugs to be part of that reform.

But I believe that we cannot afford any rich, new benefit without eventually either having to tax people more or having to commit more of our Federal budget to health care.

I do believe that there is a need to provide this benefit and I believe that we will. The question before us, is how to do this in a responsible way. I think the attitude is to do it in a way that does not increase taxes. It seems to me that a targeted approach to adding a drug benefit is the best solution, and we need to provide this benefit in the context of reform.

Dr. Gluck, based upon your testimony, it is a minority of beneficiaries who bear most of the drug cost. I think you indicated that 4 percent of the beneficiaries have expenses that exceed $2,000 per year. You also state that low-income beneficiaries, those at 200 percent of poverty or less, are more than twice as likely as better off beneficiaries to lack supplemental insurance.

One approach to targeting this benefit would be to design a catastrophic benefit to cover costs that exceed a certain amount, say,

$2,000. However we do this, are we helping those low-income people who need it the most since this is still causing them to bear the first $2,000?

Dr. GLUCK. They still would be liable for that first $2,000. As you point out, this is a population of very modest income. Other approaches include trying to couple that catastrophic coverage with some help at the lower end with people with more modest drug expenses.

What we found in our research is that the help that you provide at more modest levels, even though it helps more people, over the long term, costs less.

Senator GRASSLEY. If we target low-income seniors, are we less likely to encounter the problem of substituting private dollars that currently go towards prescription drug coverage for Federal tax dollars? I ask this, because it seems to me that this is the sort of population that is least likely to have any sort of supplemental coverage.

Dr. GLUCK. Yes. Assuming that you are not going to be absorbing Medicaid coverage or State programs, like we have heard about here this morning. Then you would be targeting the benefit towards people who currently do not have coverage. It is the near-poor who do not qualify for Medicaid or the State programs who make up a large portion of those without drug coverage.

Senator GRASSLEY. I would ask Ms. Dummit, and you as well, Dr. Gluck, but her first. We know that the estimates for prescription drug benefits vary widely depending on the design of the benefit and who is covered.

One of my concerns is that we may be relying on a strong economy surplus as the current level of Medicare savings, which may not be sustainable to finance the benefit. How can we craft a benefit in a responsible manner and avoid financing disasters if the economic picture would change?

Ms. DUMMIT. Well, I know that this committee has heard the comptroller general speak about just those issues in terms of the rising costs facing the Medicare program, and adding a prescription drug benefit clearly would add to those problems.

I think that what you are talking about in terms of targeting for particular beneficiaries would constrain Medicare's exposure, if you will, adopting certain cost control techniques to gain discounts from manufacturers in the prices that Medicare pays, and then exploring mechanisms to control utilization or to focus utilization for those that do have the Medicare coverage. The bottom line is, there are no easy ways, once this is a covered benefit, though, to control Medicare's exposure.

The CHAIRMAN. Senator Chafee?

Senator CHAFEE. Thank you very much, Mr. Chairman.

I would address this to the panel as a whole here. First of all, I, like, I guess, every member of this committee, strongly believe in prescription drugs for our seniors under Medicare, for the reasons that have been set forth here today.

But the problem is paying for it. The program now, absent whatever the additional amounts will be for prescription drugs, is predicted to go broke in the year 2015. Obviously, without doing some

savings somewhere in the program, the prescription drugs, it is going to be much earlier.

Now, there is another factor in here. First, I would ask if you would agree with me. If we make the prescription drug available to everyone, then those employers who are currently providing it for their seniors are going to stop doing that.

I presume the attitude is going to be, they are covered by the program, so why should I, Mr. Employer, incur the expense? Not every employer does it, so why should I, the good employer, do it when the government is going to pay for it anyway? Would that follow, yes or no?

Ms. DUMMIT. It sounds like a safe assumption.

Senator CHAFEE. Now, there are three suggestions that have come up that I am familiar with to save money under the program. One, is to increase the age of eligibility to conform with Social Security, which is not true now. Social Security's age of eligibility, as you know, will advance up to the age of, I believe, 70, not too far in the future.

The second, is to means test the Part B premium. Why should this program be paying for the doctors' visits for wealthy retirees? Third, to provide some co-payment for home health visits.

But let me try you out on the means testing of the Part B premium. What do you think of that, Mr. Concannon? Are the mechanics of it just very complicated?

Mr. CONCANNON. I would say it would be very complicated. Obviously, I think, as all of the members here are aware, one of the broad supports for Medicare is that it is universal. Once you start getting into means testing programs, it gets more complicated to administer, and also, you lost public support correspondingly.

So it would be possible to do it, but I would say it would be very challenging to start means testing. I would see more possibility in just some sort of a co-payment that rises as one's income rises as preferable, but I have not really given enough thought on the means testing side.

Senator CHAFEE. Dr. Gluck?

Dr. GLUCK. Well, in addition to the administrative questions there is also a question of what level you begin the means testing, and how much. We know this is a population with relatively modest means. So in order to significantly enhance the financing picture, my understanding is, you need to move fairly far down the income scale.

Senator CHAFEE. All right. So we reject that. We reject the increase in the age of eligibility. But what do we say about the costs of the program? It is no secret that the costs look dismal when you look out at 2015. You say, 2015; that is a long ways away. Well, it is not so far away. So what do you suggest?

Dr. GLUCK. In the prescription drug area, I think this is——

Senator CHAFEE. And, by the way, do you agree that the employers will drop it, probably?

Dr. GLUCK. Yes. That would be a rational thing for them to do.

Senator CHAFEE. So the cost will increase more than just adding the benefit to those 35 percent who currently have nothing.

Dr. GLUCK. You would shift those costs. In the area of prescription drugs, this is an area that may be ripe for experimentation

with new means of cost control, borrowing from what States and the private sector are doing, and, as I suggested before, looking at experimenting with competitive purchasing.

Senator CHAFEE. What do you say, Ms. Dummit?

Ms. DUMMIT. I think, as to the overall increases in Medicare spending, certainly the Balanced Budget Act went far to improve the financial situation of the Medicare program, generally.

I think that it is likely that there are further improvements that can be made in terms of the way Medicare pays providers. I would think that, similarly, if there were a Medicare drug benefit, it would need to be designed in such a manner that there could be changes over time to respond to the rising costs.

Senator CHAFEE. Well, my time is up. I am a Hancock County man, Mr. Concannon.

Mr. CONCANNON. Thank you, Senator.

The CHAIRMAN. Senator Breaux?

Senator BREAUX. Thank you, Mr. Chairman. Thank the panel. I would like to associate myself with Senator Chafee's line of questioning. I thought they were right on target, except on the Social Security age increase. I think it goes up to 67, not 70. I mean, that gets us into a lot of trouble when you start talking about that. I think 67 is difficult enough. But the point is well taken, what you were trying to say.

The point we have before the committee, I mean, we are considering adding money back to the program from the BBA 1997 cuts. That is one thing that we are considering in this committee, I take it. We are also now considering adding a drug program to Medicare.

I think it is incredibly important, and while we talk about doing more with the program we also are serious about fixing the program. I mean, if we are going to do these other things, which I wholeheartedly support, we should not do them separately.

Are we going to do an add-back to the program, are we going to add pharmaceuticals to the program? We certainly should, at the same time, in one single package, offer serious reform to the program. We cannot sustain it today.

As Senator Chafee and others have said, it is going broke by the year 2015. It is projected to have the premiums for seniors double by the year 2007. These are unsustainable numbers. So, it is really easy to talk about adding prescription drugs. That is easy. That is fun. That is very important. I strongly support it.

But if we do not figure out a way to reform the program and to pay for it, we are not serious. We could talk all day about adding more drugs to it, but unless we reform it at the same time, we are going to get ourselves in a situation that is even more of a problem than it is today, and that is hard to actually conceive.

So if we are going to add prescription drugs, which I wholeheartedly support, it has to be done in the context of reforming the program, otherwise it is very meaningless.

Let me just ask the panel for some comments. We struggle with this. Everybody is struggling with it. I noticed in the paper this morning, our good friend John Podesta had a statement yesterday on what the administration is doing in this area. It shows you their problem. It says, "The White House Chief of Staff said the poorest

people under their proposal would not have to pay the full monthly premium that is expected to be imposed on senior citizens in order to give them prescription drug benefits. Some people would get help with the premium at the lower end of the scale, but the premium will be fixed, Podesta told the Associated Press."

He said the prescription drug plan that the administration is working on would be universal and affordable, but he did not say how much it would cost, he did not say how the President proposes to fund it, and he did not say what the income cut-off would be to qualify for the lower premiums.

So, I mean, obviously they are struggling with the concept, yes, we want to do it. How we do it, we do not know yet. That is where everybody happens to be.

Let me ask you to comment on what the commission did in our proposal, which was the one that was out there. What we had suggested in the final proposal was that, for the first time, all beneficiaries up to 135 percent of poverty, which would include all the QMBies and all the SLMBies, would receive drugs free of charge, no premium, for the drug program.

That would cost about $61 billion over 10 years, is what it was scored as costing. That means people up to about $11,000 a year would get prescription drugs free, and the Federal Government would pick up the States' extra burden on that.

We also said that all Medigap plans would have to offer prescription drugs. Instead of just having three of them offering, that everybody would have to offer it, hopefully lowering the cost because everybody is participating.

The third thing we said was, in addition, we would require fee-for-service beneficiaries who do not qualify for the 135 percent below subsidy would have access to drugs through a high-option plan that HCFA would have to offer. We did not recommend that it be subsidized. I think it should be. The question is, how much, how do we pay for it, and should it be means tested? So that is what we had out on the table.

I would just ask all three of you to comment on that. Ms. Dummit?

Ms. DUMMIT. Well, I think that certainly targeting those near-poor who do not qualify for Medicare is an effective strategy to get the drug benefit coverage to those who probably need it the most. Medigap coverage, as you said, if all plans were required to cover drugs, would help address some of the adverse selection problem you have seen. What that would do to overall premium increases, however, is still unknown.

As to a high-option plan for those other beneficiaries still in the fee-for-service program, as we have been talking, that depends on the details on how that would be structured.

But the Medicare program, being such a substantial share of the market, could use that market power in terms of negotiating discounts. How it would also manage to use that market power wisely to totally not change the way things work on the market too drastically now, is the other question.

Senator BREAUX. Thank you.

Dr. Gluck?

Dr. GLUCK. In addition to what Ms. Dummit said, I would agree that the details are important. On the fee-for-service high-option, one question would be, would there be enough adequate protections against the sort of risk selection that we have seen in the Medigap market.

Senator BREAUX. Mr. Concannon?

Mr. CONCANNON. Briefly, I am very attracted to the 135 percent below. That is what our Drugs for the Elderly program has been in Maine, for all the reasons that are cited.

But to your larger question about reforming the program, an under-explored area, in my view, is the issue of dual eligibles. The New England States, each of the six Health and Human Service Commissions, we have been in dialogue with HCFA now for about 2 years around the convergence of heavy costs with patients who are both dually eligible for Medicare and Medicaid. It does not solve the dilemma that you have as a Senate. But it is an area that I think we could do better for those patients and actually save some money, if these were not operated as sort of separate a silos right now.

Senator BREAUX. Thank you.

The CHAIRMAN. Senator Conrad?

Senator CONRAD. Thank you, Mr. Chairman. I thank the panel as well.

Every time I go home and do a community forum on this subject, people come up to me afterwards, often elderly women who are widowed, and show me their budgets. I remember, at one of my recent meetings an elderly woman came up to me and showed me, her entire income was $550 a month.

One of her costs was over $150 a month for prescription drugs. It is not at all unusual to have somebody pay $400 or $500. I have even had people come to these meetings who show me their bills for prescription drugs. I remember one man came and showed me his wife's costs, over $2,000 a month for prescription drugs.

Now, there are not many people that could withstand that kind of cost without either an insurance policy of some kind that was paying for it or some kind of government program that was helping to pay for it. Two thousand dollars a month would put most families under very quickly.

The question, as has been described here by Senator Moynihan and Senator Mack, is the practice of medicine has changed. My grandfather was a pioneer surgeon in North Dakota, started the clinic, and was chief of staff of the hospital. When they practiced they did not have much in the way of medicines to provide to patients. But that has changed, and it has changed dramatically.

I have a father-in-law right now that is alive because of the miracles brought by prescription drugs. It is phenomenal, what they can do. And it is burgeoning. I was just reviewing the money spent on research last year: $24 billion spent on research by the drug companies.

That leads me to my question. North Dakota, the State I represent, is right on the Canadian border, as is yours, Mr. Concannon. Canada is paying half as much for the same prescription drugs as what we pay. One-half as much, the same drugs.

As I understand it, the differences are, we have much tighter requirements, much stronger patent protection than they do. And they have price controls. That is what I have been told. I do not know the device they use.

My question is, if we were to have something put in place that controlled prices, how would we prevent there not being a sharp reduction in the research dollars generated by these companies that is leading to such a rapid advance in terms of the science? Any of you thought about those issues, or have a reaction?

Mr. CONCANNON. The only thought, Senator, I have in that regard, again, talking to physicians and the pharmacy consultants in our Medicaid program, they tell me that there is a lot of research expended on look-alike drugs, me too.

A drug company has a successful drug that its competitor has spent a lot of research money and time basically creating the same drug, with minor variations, to be competitive. In a world of limitations, is that beneficial to the American people?

I think the whole research and development issue, much of that is essential and important, but a lot of it is simply, again, expended for look-alikes and me too drugs that really do not add anything to the armament of medicine.

Senator CONRAD. Do you have any research on, of the $24 billion that is being spent a year on research, how much of it would be for these so-called me too drugs?

Mr. CONCANNON. I do not know.

Senator CONRAD. Dr. Gluck?

Dr. GLUCK. I do not have an answer to your question. But I do know that it is an area where we do need good, independent research and more attention. I think one of the benefits of the discussion about prescription drugs over the last several months is, it has raised the visibility of the issue and we have a better idea of what more we need to know.

I am encouraged that, over the next couple of years, we are going to be hearing of more good research that may aid in these sorts of decisions that you are going to be making.

Senator CONRAD. Ms. Dummit, any comment you would want to make?

Ms. DUMMIT. Well, I would like to point out that some sort of price controls in conjunction with a Medicare prescription drug benefit could affect the revenues for pharmaceutical manufacturers in two ways.

First of all, we might expect utilization to increase because the information data indicates that, when people have drug coverage, they use more prescriptions. So, there could be a boost in revenues in that sense. However, certainly, price controls could have the opposite effect on revenues for manufacturers.

As to how they would, in that new environment, weigh the benefits internally of continuing their current level of research and development versus other needs for those companies, they are going to be internal business decisions. But, as Dr. Gluck said, we do not have the kind of information now to evaluate those kinds of decisions.

Senator CONRAD. Let me just say, I am not a fan of price controls. I think the economic history of price controls is not very encouraging. I thank the panel.

The CHAIRMAN. Senator Bryan has graciously agreed to yield for a question by Senator Hatch.

Senator BRYAN. For one Federal judge, Mr. Chairman. [Laughter.]

The CHAIRMAN. The deal is agreed to. [Laughter.]

Senator CONRAD. It seems like a reasonable request.

Senator MACK. Can we all get into the bidding here? [Laughter.]

Senator HATCH. I wish you would treat me with a little more dignity than that. [Laughter.]

The CHAIRMAN. All right, Mr. President. [Laughter.]

Senator HATCH. That is much better, is all I can say.

First of all, let me thank you, Mr. Chairman, and the Ranking Member, Senator Moynihan, for holding this hearing today. This is a very important issue for all Americans, so I welcome today's hearing. It is an important first step in improving Medicare's drug coverage policy.

Now, my question is directed to the witness from the GAO, Ms. Dummit, and the National Academy of Social Insurance. As we examine proposals to cover prescription drugs as a benefit under Medicare, I am very concerned about how this benefit is going to be structured and financed.

Clearly, we need to be sure that there would not be any unintended consequences that would inhibit the development of the so-called breakthrough pharmaceuticals or drugs in the future.

We do not want, it seems to me, to implement a policy that will hinder innovation and development of new pharmaceutical products. Nowhere in medicine is the prospect of curing and treating disease more promising than in the field of pharmaceutical research and development, which I think Mr. Concannon has indicated here today in his experience in Maine.

Last night, I had the honor of co-chairing the tenth anniversary of the Elizabeth Glazier Pediatric AIDS Foundation. I, along with my co-chair Senator Boxer, raised more than $2 million last night for the foundation, which is doing extraordinary work in funding research to treat children with HIV and AIDS. They have raised $75 million since we raised the first million dollars. Senator Metzenbaum and I held a dinner 10 years ago to raise their first million.

It is just unbelievable, what they have done in the Pediatric AIDS Foundation, because a child born with HIV did not have much longer to live than the age of four 10 years ago when that organization came into existence.

Today, thanks to the research and development in the pharmaceutical industry, a child born with HIV is expected to live well into their teens, and in some cases, even longer. But we have to do even better.

Five hundred thousand children are dying every year from AIDS, and this is just one malady that I am mentioning here. The situation is getting worse, particularly in Africa. Imagine what will be available in treating or curing AIDS 10 years from today.

So, I am very concerned about any effort that may inhibit the development of new drugs. I think we need to be very cautious to ensure our actions are not counterproductive. In our zeal to try to do something good, we may be counterproductive to the future, and I do not want to see that happen.

So it seems to me that there needs to be more analysis on the impact of drug development, particularly if the government-controlled drug benefit is passed. I would appreciate both of your additional thoughts on this issue, particularly from you, Ms. Dummit, the GAO witness.

Ms. DUMMIT. Well, the trade-offs and concerns you mention, I understand. The issue is how pharmaceutical companies make internal decisions regarding research and development, particularly when they face the potential that the market would change, as it most certainly would if there were universal Medicare prescription drug benefits that included some sort of price controls or ways to control utilization, or shift spending among different kinds of drug products.

So the information we have available is pretty limited in terms of assessing what the future impact of those kinds of controls and the changes in utilization would be. We are very hampered in this regard with respect to what would happen, the result.

Senator HATCH. But you are as concerned as I am about it, I am sure.

Ms. DUMMIT. Certainly.

Senator HATCH. Dr. Gluck?

Dr. GLUCK. There certainly are no technologies that we can take off the shelf about how to price drugs, how to structure this benefit in such a way where we know what the effects would be on R&D. It certainly makes sense that drug companies are going to make their business decisions in response to whatever Congress does.

I, again, think that this is an area where we ought to be doing some experimentation and trying different methods of structuring the benefit of determining prices to see if we can do a bit better job than we would otherwise in anticipating some of those unintended consequences.

Senator HATCH. The thing I am concerned about, and there are a lot of things that I am concerned about in this area, but I want to keep the innovation going. I want to keep the huge amounts that pharmaceutical companies are investing in research and development going.

I want to be able to find these breakthrough drugs, not just for AIDS, but for so many other maladies that we suffer from in our society, and which really will save us monies in the long run.

If you put in and impose price controls, even though some people will say these are not price controls, but indirectly they will become that, if you impose those, then of course in the end we could run up the cost of the drugs in the end and not have the pharmaceutical breakthroughs that we really need to have.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Bryan?

Senator BRYAN. Mr. Chairman, I thank you. Before our able friend, the chairman of the Judiciary Committee, leaves, I believe

that that was probably a two-judge question. [Laughter.] Senator Mack and I have had a discussion on that.

Senator HATCH. We will see what we can do.

Senator BRYAN. Thank you very much.

The issue that we confront in this whole host of hearings that the Chairman has convened in Medicare, probably nothing has resonated more with the constituents that I represent than the question of prescription drugs. You hear it constantly. Constantly.

This past Saturday I was in northern Nevada in Washoe Valley, and an elderly gentlemen, but obviously very well informed, engaged me in some conversation on the subject. Senator Conrad touched upon this briefly, and perhaps others have before I joined the hearing.

But his assertion was that the identical drug can be obtained in either Canada or Mexico at substantially less cost. And he was not talking about marginal differences, a third to a half.

I guess the question I have is, does the data base support that proposition? Is it the identical drug by the identical manufacturer? Are the cost differentials that substantial?

Mr. CONCANNON. Yes, they are, Senator. That is our experience. Be mindful, I spent a number of years as a public mental health official. Clozeril is a highly-effective psychiatric drug that has actually allowed many people a miraculous kind of recovery.

That drug was sold for $2,500 or $3,000 in Europe for many, many years. When it was introduced in the U.S., it was twice the cost. The same Sandoz manufacturing, international firm. So it is a pricing decision that is made. We see that next door to us in Canada.

Senator BRYAN. And you are saying that, generally, it is fairly widespread. It is not just a particular drug, but it is fairly widespread, in your judgment.

Mr. CONCANNON. It is. An example in Maine. A couple of years ago, two busloads of seniors citizens went to Montreal, got their Maine physician to prescribe their drugs, had a corresponding physician in Montreal who would rewrite the scripts. The difference in the price of the drugs that they ere paying paid for their trip to Montreal.

Senator BRYAN. The general public may not have access to the distinguished witnesses like yourself and the ability to convene a hearing such as this, but the public in America is getting gouged. That is what our constituents tell us.

I think, as most every member of the Congress, I favor providing a prescription drug benefit. The difficulty is obviously the cost. How are we going to pay for it? At the same time, we are debating Medicare reforms.

If I might ask you a question, Dr. Gluck. The information that I get from these same seniors we are talking about is that, in effect, these Medigap policies are extraordinarily expensive, and that the trend line, if we do nothing, is that even these policies, more costly as they are becoming, will provide less coverage, less protection in terms of the prescription benefits that may be available in the future with new breakthroughs in various medications. What does the trend line tell you?

Dr. GLUCK. The premiums for Medigap policies are going up across the board, but the increases have been particularly high in the 3 of the 10 policies that include prescription drugs, the HI and J policies.

As the price goes up, fewer folks can afford it. One of the major reasons why the prices on those policies are particularly high, is that those folks who really do need the prescription drugs are the ones who are most likely to buy it.

Senator BRYAN. That obviously argues that if we broaden the base so that the risk adjustment factors are most broadly based, that presumably the costs would come down. Is that correct?

Dr. GLUCK. And Medicare is really the ultimate way of spreading that risk across the whole country.

Senator BRYAN. Spreading that risk.

We have done a number of things to try to extend coverages for certain populations. It is very difficult with respect to the less affluent groups to get them to participate in these programs.

We have provided $24 billion, as you will recall, to provide some help for those who are above the Medicaid threshold, but not in a position where any reasonable person would suggest that they could afford to buy health care coverage. The experience in my State is that we have made very, very little progress in getting those people to come in and to participate in these programs.

Ms. Dummit, would you care to comment on that, as it relates to what we might be doing at the State level in terms of any kind of assistance to provide prescription coverage for these people?

Ms. DUMMIT. Well, I know that the GAO just came out with a report stating that many of the beneficiaries who are eligible for the QMBie or SLMBie protection are not taking advantage of that.

I have red that some have speculated, however, that if that coverage were to include prescription drugs, which is a very valued benefit, that more people might avail themselves of that coverage. Whether that is true or not, remains to be seen.

Senator BRYAN. Well, thank you very much.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Bryan.

Senator Jeffords?

Senator JEFFORDS. Thank you, Mr. Chairman. I am sorry I was delayed. It seems like whenever you have three important things, they always arrive at the same time. This morning I got four: the bill of rights, and agriculture, and education, as well as being here.

I am committed to working as hard as I can to see that any Medicare reform proposal considered by the committee includes a prescription drug benefit. We must take action to make sure that prescription drugs are more affordable for more of our senior citizens.

I have heard too many stories of seniors going without medication simply because the costs are too high and they cannot afford it. In my opinion, it does not make sense to reimburse hospitals for surgery, but not provide coverage for the prescription drugs that might prevent surgery.

I am also developing my own legislation for insurance coverage for prescription medicines for seniors who do not qualify for Medicaid or other supplemental drug coverage.

Also, I would just echo the Senator from Nevada. I live in Vermont. We are right on the boundary. It seems to me, we have to look at how the rest of the world can help take care of the cost of the research and development, and not our citizens just trying to do it mostly by themselves.

Dr. Gluck, in your studies, have you considered how much would be saved in other areas of Medicare by an effective prescription drug program?

Dr. GLUCK. We have not. There is not systemic data to tell us what would happen in the whole system. There are some clues for some parts of the population.

For example, there have been some studies of the Medicaid population that have showed that, for low-income individuals, providing them health insurance for their prescription drugs leads to not just better health outcomes, but prevents problems down the line. It really varies, both by the drug and also by the condition. For example, you could imagine two Medicare beneficiaries with heart conditions.

Their physicians prescribe them a medication to keep them healthy. The first one does not take it, and perhaps dies of a heart attack. Besides that awful outcome, he does not cost much money. If he had taken his medication, he would have lived longer and might have used other health care services.

In another case, though, you can imagine someone not taking their medication and perhaps having a stroke, and in that case they may require very expensive care after that stroke and, in addition to not having their health, they would be costing more money.

So in those two situations, you can see it sort of can go either way. Unfortunately, we do not yet have the data to say what would happen for the Medicare population as a whole.

Senator JEFFORDS. Any comments from the other two?

Mr. CONCANNON. Just to agree with Dr. Gluck's comment on people being at risk of a stroke. We get letters from people and we hear from our public health nurses working with older folks who are taking a medication for their high blood pressure condition, expensive medication, that they have a tendency to skip days. They say, well, I will just take it every other day, as a way of trying to extend the life of the prescription and its cost. But, in so doing, they put themselves at risk of having a stroke, and then it requires very costly rehabilitation if it does not kill them.

So we hear anecdotes that way, but we ourselves have not been able to sort of isolate that cost trade-off. We are certain that it has some impacts. I mentioned earlier this morning that the availability of medications on both Medicaid and the drug benefit program for the elderly is one of the factors—not the only factor, but one of the factors—in a 20 percent reduction in Maine in residents of nursing facilities from 1994 to 1999.

Senator JEFFORDS. Well, I agree with Senator Moynihan. We are going through a real change here in the whole area of medical care. This committee, I am sure, will pursue what those changes are and what they are going to lead to.

Also, again, I do not expect you may have any information, but where our pharmaceuticals are developed in other nations—as you

know, we have had a lot of problem with going overseas because of some of our restrictions, et cetera.

How do they recoup their R&D costs in other nations? I know it has to do with their copyrights and all, but do they get others to share or do they take it all on the chin in the country where they are developed? No information?

Dr. GLUCK. There are others who are probably more expert on that than I.

Senator JEFFORDS. All right. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

I want to express my great appreciation for the excellence of the testimony of this panel. We will continue to call on you. We invite and urge you to provide any additional information that you think will be helpful as we try, according to Senator Moynihan, to update and modernize this most critical problem. Thank you very much for being here.

It is now my pleasure to welcome the second panel, a group of distinguished witnesses who will address pharmaceutical issues from both industry and beneficiary perspectives.

Our first witness will be Morris B. Mellion, M.D., a senior vice president for Health Care Policy and chief medical officer of Blue Cross/Blue Shield of Nebraska.

Next, will be Jeff Sanders, a senior vice president of PCS Health Systems, Inc., who will discuss the use of pharmacy benefit managers.

He will be followed by Alan F. Holmer, the president of the Pharmaceutical and Research and Manufacturers of America. Next, J. Leighton Read, M.D., the chief executive officer of Aviron, who will speak on behalf of the Biotechnology Industry Organization.

Finally, we are very pleased to have Martha A. McSteen, who is president of the National Committee to Preserve Social Security and Medicare, who will present the beneficiaries' perspective.

It is a pleasure to welcome each and every one of you. As I have said, your complete testimony will be included as if read. We ask that you keep to five minutes.

We would be happy to start with you, Dr. Mellion.

STATEMENT OF MORRIS B. MELLION, M.D., SENIOR VICE PRESIDENT FOR HEALTH CARE POLICY AND CHIEF MEDICAL OFFICER, BLUE CROSS AND BLUE SHIELD OF NEBRASKA, OMAHA, NE

Dr. MELLION. Thank you. Mr. Chairman and members of the committee, I am Dr. Morris Mellion, senior vice president for Health Care Policy and chief medical officer of Blue Cross/Blue Shield of Nebraska. Thank you for the opportunity to testify about prescription drug benefits and the Medicare program.

I am a family physician. Today I will be testifying on behalf of the Blue Cross/Blue Shield Association. Blue plans recognize the importance of pharmaceuticals to the prevention and treatment of disease. But the cost of providing drug benefits is high and is accelerating at unprecedented rates.

Blue plans' aggregate spending on outpatient drugs increased by almost 60 percent from 1993 to 1998—that is in spite of attempts to control expenditures—from $7.6 billion to $12 billion.

At Blue Cross/Blue Shield of Nebraska, one of our large cell-funded customers asked us to explain why its pharmaceutical costs were rising so rapidly. When we compared the company's pharmacy expenditures in 1996 with 1998, we found that the average number of prescriptions per member had risen from 8.2 to 9.4.

The average brand drug prescription costs had increased from $43.36 to $57.72. The use of generic drugs had declined 3.5 percent. More alarming, the average prescription cost per member had climbed from $188.21 to $319.13.

Why are prescription drug costs increasing so rapidly? First, the baby boom generation is aging. Older individuals require more prescription drugs to treat chronic and disabled diseases.

Second, new drugs are being developed and tested at an unprecedented rate. Many treat previously untreatable conditions. As a physician, I am truly torn. I am excited about these new discoveries and the hope that they bring, but I am worried about whether the added cost they represent will decrease the number of people who can afford to pay premiums.

Third, direct-to-consumer advertising raises costs by stimulating both increased drug consumption and selection of higher-priced drugs. Spending on direct-to-consumer advertising reached $1.3 billion in 1998. Finally, recent consolidation in the generic drug industry have resulted in many generic drug price increases.

What are the health plans doing currently to address rising prescription drug costs? Blue plans and other private health plans are using formularies, lists of drugs that a plan will cover.

In some plans, the coverage is recommended or incented. In a few, it is mandatory. Most plans have committees of physicians and pharmacists who review the clinical effectiveness, safety, and cost of drugs, and then determine their formulary status.

Many health plans negotiate discounts by contracting with retail pharmacies. Often, large pharmacy chains and networks with small pharmacies will discount prescriptions in return for inclusion of all their stores in a plan's pharmacy benefit program. Some plans use mail-order pharmacies to obtain volume discounts.

I must add that, in rural areas such as Nebraska where pharmacies may be in towns 40 to 50 miles apart, Blue Cross is committed to a reimbursement level which will support the viability of local pharmacies. In most towns, the real issue is access.

Finally, many plans are implementing multi-tiered co-payment structures to encourage members to choose drugs that are both clinically, and cost, effective. This strategy may be effective where there are valid therapeutic alternatives, but it does not address new breakthrough drugs which represent a major improvement in care.

I would like to comment briefly on legislative proposals this committee may consider. Some Federal policy makers have advocated requiring all 10 standardized Medigap plans to cover prescription drugs.

While the intent of the proposal is laudable, a recent study by the Blue Cross/Blue Shield Association and the Health Insurance Association of America found that it may be self-defeating. The study revealed that the proposal would increase Medigap pre-

miums by over $1,000, thereby making Medigap coverage unaffordable for many senior citizens.

Some policy makers in Congress and the administration are also considering adding pharmaceutical coverage to Medicare's core benefits. The Blue Cross/Blue Shield Association shares Congress' concern about ensuring access to prescription drugs, but we urge Congress to proceed with caution because of the challenges that we in the private sector are currently facing in trying to contain the drug costs.

Thank you again for the opportunity to testify today.

[The prepared statement of Dr. Mellion appears in the appendix.]

The CHAIRMAN. Thank you, Dr. Mellion.

Mr. Sanders?

STATEMENT OF JEFF SANDERS, SENIOR VICE PRESIDENT, PCS HEALTH SYSTEMS, INC., SCOTTSDALE, AZ

Mr. SANDERS. I am Jeff Sanders and I am here representing the Pharmaceutical Care Management Association. I am senior vice president of PCS Health Systems, one of the largest pharmacy benefit managers.

As an aside, I used to work for Senator Domenici on the Budget Committee staff, and at HCFA on legislative issues. Mr. Chairman and members of the committee, I sincerely appreciate the invitation back. It has been 6 years.

The Pharmaceutical Care Management Association represents managed care pharmacy benefit companies, or PBMs, and their partners in pharmaceutical care. PCMA's 140 members serve more than 150 million individuals and employ more than 9,000 pharmacists.

Over two-thirds of the 2.8 billion prescriptions now dispensed annually are covered by managed health care. That is in direct contrast to 1991, only 8 years ago, when only one-third of prescriptions in this country were covered by managed health care.

PCS Health System itself manages and monitors over 300 million individual prescriptions each year. Our customers include 5 million Federal employees, 3.5 million seniors, Medicaid HMOs, Blue Cross plans, employers, and others.

PBMs are operating against the backdrop of quickly-rising pharmacy costs. For the insured populations, trends were 14 to 18 percent in 1998, and look to be accelerating slightly. Only about 3 percentage points of this increase are attributable to price increases on drugs. The remaining cost increase is due to utilization and intensity. Intensity is the substitution of more expensive, stronger, or better drugs for less costly drugs.

In my written remarks I have included a summary of PBM services and programs, as well as appendices that contain information from PCS studies on why pharmaceutical costs are rising so quickly, and specific drug use patterns and trends in the senior population we serve.

I want, however, to focus mainly on the value of PBMs and the implications for a Medicare drug benefit. First, PBMs ensure quality pharmaceutical care. Clinical considerations and quality of care come first for successful PBMs.

For example, most PBMs provide drug safety alerts online, which allow the dispensing pharmacist to identify and resolve issues before the patient obtains a prescription. PCS alone sent alerts on 5 million potentially dangerous drug interactions in 1998.

PBMs also provide ad hoc quality efforts. I think many of you may have been aware of the press reports on Viagra's dangerous interactions with drugs containing nitrates, people dying.

PCS studied its data base so that we could alert physicians to the danger. Carefully complying with privacy concerns, we made the information actionable by identifying for physicians any of their patients using both Viagra and nitrates. We believe there are many cases where such a service has saved lives and improved the quality of care.

Second, PBMs produce savings. Much like was mentioned with Medicaid programs, GAO did a study in 1995 that showed savings in the Federal employees' plan ranged from 20 to 27 percent. Depending on the plan, we have shown savings considerably higher than that.

Increasingly, however, our industry is focusing on the value of pharmacy benefits within overall patient care. Studies regularly show that up to 25 percent of all elderly hospital admissions result from poor patient compliance with drug therapy, misuse of drugs, prescribing errors, drug-drug interactions because different physicians unknowingly prescribed drugs that chemically interact with each other. In fact, statistics would be much worse without our current programs.

Finally, PBMs make the benefit patient-friendly. Surveys consistently show that pharmacy benefits rank high in what members like most about their overall health care plan. As part of the previously described study on PBMs in the Federal employee program, GAO found patient satisfaction that ranged from 93 percent to 98 percent.

Many issues remain in managing a pharmacy benefit. With more new pharmaceutical compounds reaching the market today than at any time in our history and many more of these compounds representing breakthroughs, the challenges of managing a pharmacy benefit and containing costs are also changing more rapidly than ever.

PCMA, the Pharmaceutical Care Management Association, is proud of the contributions that we have made. We believe that the innovation that our industry regularly provides will continue to provide greater savings, add clinical value, and allow us to accomplish these goals in a way that we feel will be less intrusive to patients and physicians than many of today's medical and pharmacy interventions.

What does this mean for a Medicare prescription drug benefit? We think it means that services of PBMs or managed care plans that provide services like what independent PBMs do should be made a part of the Medicare program.

The health care environment is characterized by diversity in patient and provider sectors. Consequently, we think a single approach is probably not the right way to go, and multiple approaches need to be supported in the structure of this benefit. There is a huge amount of innovation and competition in our in-

dustry. It depends on the ability to allow some variation. Thank you.

[The prepared statement of Mr. Sanders appears in the appendix.]

The CHAIRMAN. Thank you.

Mr. Holmer?

STATEMENT OF ALAN F. HOLMER, PRESIDENT, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WASHINGTON, DC

Mr. HOLMER. Mr. Chairman, Senator Moynihan, other Senators, it is a pleasure for me to be back before this committee. Also, thank you for the opportunity to present the views on behalf of the American Pharmaceutical Industry.

Any time any patient is unable to obtain access to our medicines, our companies are concerned. This is why the pharmaceutical industry supports expanding prescription drug coverage for seniors. We think it should be done through a strengthened and improved Medicare program that gives beneficiaries good choices between different kinds of competing health plans.

We want to be part of the solution. We want to help seniors obtain the medicines they need without discouraging biomedical research to help and heal patients.

I think you started off this hearing just right, Mr. Chairman. You said this is a promising and important matter. Senator Moynihan, you said we are dealing with a good development here. I agree. But he challenge that you really face is best illustrated by a sign over the counter of a local print shop. It warns customers: "Price, Speed, Quality: Pick Two."

In my testimony, I lay out a series of questions and principles about any proposal before the committee. For example, will it strengthen and improve the Medicare program or will it just tack on an expensive drug benefit to an out-of-date program on its way to insolvency? Does it encourage integrated care?

For cost containment, does it rely on competition among private health plans or does it rely on government-imposed price controls? Who will run the program, HCFA, with its 132,000 pages of regulations and manuals and government price controls and red tape? Will it expand choices in medicines for seniors or will it ultimately lead to restrictions on access to medicines? Finally, will it harm biomedical research?

What about the proposals before this committee? First, the premium support proposal supported by a majority of the Medicare Commission. We are encouraged. Senator Breaux, we think you are on the right track. Your approach stacks up well against our principles.

In my testimony, I also describe our concerns with respect to other proposals before the committee and I would be happy to respond to questions. But, inevitably, many of the command-and-control big government approaches would stifle innovation and would lead to restrictions on access to medicines. What we need is more choices for seniors, more access, more coverage. What we do not need, is more restrictions, more bureaucracy, more government red tape.

Finally, if I could, Mr. Chairman, I would like to close on a personal note. I have shared with you my views today as president of PHARMA. I would also like to share with you my views today as a dad. As a number of members of the committee know, I have two children, both of whom have cystic fibrosis. Senator Breaux, you come out and play tennis with us every year to raise money; Senator Chafee, you have been there.

My son Scott is a sophomore at Georgetown University, his sister Joy is a junior at Langley High in McLean. They are both doing wonderfully, thanks, in large part, due to the pharmaceutical industry. But a child with cystic fibrosis has a life expectancy of 31. There is no doubt in my mind but that a cure for cystic fibrosis will be found within my lifetime. What I do not know is whether a cure for cystic fibrosis will be found within the lifetimes of my children.

Now, why do I talk about my teenagers in a discussion about drugs for seniors? Because this debate is really about quality health care for all Americans, which depends on private industry's continued drug discovery and development. Seniors want and need our medicines because they were invented.

So, Mr. Chairman and all Senators, if I could leave you today with only one message, let it be this: at some point in the not-too-distant future, a Congress will pass, and a President will sign, legislation to expand drug coverage for Medicare beneficiaries.

It is going to happen, and we want to be part of the solution. Some say that this issue is life or death for the pharmaceutical industry, American's premier high-technology industry.

After the debate is over and the dust has settled we will still have a pharmaceutical industry, but depending on what you do, the industry could be profoundly different and the results for patients could be demonstrably less. As the debate unfolds, I hope you will remember the millions of Americans, like my children, who are waiting impatiently for new cures and treatments.

We can provide quality health care for seniors, including better prescription drug coverage, but we need to do it the right way. If we do it the wrong way, the industry and the patients we serve will undoubtedly suffer the consequences.

Thank you.

[The prepared statement of Mr. Holmer appears in the appendix.]

The CHAIRMAN. Thank you, Mr. Holmer.

Dr. Read, please.

STATEMENT OF J. LEIGHTON READ, M.D., CHIEF EXECUTIVE OFFICER, AVIRON, ON BEHALF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION, WASHINGTON, DC

Dr. READ. Mr. Chairman, Senator Moynihan, and members, thank you for the opportunity to testify. I was really surprised this morning at how many of the points that I wanted to make and feel strongly about have already been made this morning, and also how little has been said about the biotechnology industry and biotechnology products. So, that is where I will concentrate my remarks.

I am chairman and CEO of Aviron, a biopharmaceutical company I founded 7 years ago to create a new generation of vaccines for

children and for adults. Our most advanced product is a flu vaccine that is given by a nasal spray. You might have heard about that.

Previously, I was on the faculty at Harvard Medical School, where I practiced internal medicine, and at the Harvard School of Public Health, where my research focused on the cost-effectiveness of new medicines back in 1979, 1980, when it was still an ivory tower kind of concept.

I have taken care of elderly patients at the Peter Ben Brigham who could not afford their outpatient prescriptions even then, and I have taken care of patients at the West Roxbury VA Hospital, where we had the luxury of a more integrated approach to managing all the inputs to their health care.

Today I am testifying on behalf of the biotechnology industry organization, representing over 840 companies and research institutions in 46 States. There are really four points I would like to ask you to consider.

Smaller biotechnology companies, many of them still years away from having commercial products, are at the forefront of discovering the next generation of life-saving medicines that we have been hearing about, including preventive and early detection technologies, potential cures for arthritis, Alzheimer's, and Parkinson's disease, and the major causes of hospitalization and death in seniors, that is, cancer, heart disease, and stroke.

Driven by entrepreneurial spirit and a sense of urgency, these smaller companies have greatly accelerated the pace of innovation. There are now 300 biotechnology products in late-stage clinical trials at this point.

The second point, is that these breakthrough medicines represent a larger and larger share of health care. We have been hearing about that. It is changing. This is not bad news. It is good news that we have people out of the hospital, avoiding surgery, and alive because of prescription medicines. It emphasizes the fact that we need to ensure access and it is part of an integrated system, is our view.

It would be a tragic failure of vision if we do not recognize that the medicines we do not have today are even more important than the ones that we do have. There has been a lot of progress, but think about the future.

I will not trivialize the current problem of people who have a problem with access to the prescription drugs of today. But less us keep something in perspective. The largest threat to seniors—really, all of us—is the virtual certainty that we are going to be living later in our life with debilitating diseases that we cannot adequately prevent today, that we cannot adequately treat. That is the biggest threat to seniors.

Now, realistically, we are not going to eliminate the frailties of aging overnight. But you hold in your hands, as we have this debate, the ability to continue this progress or the ability to retard the race towards these major diseases.

My third point, is that last year the biotechnology industry, apart from the $24 billion we heard about already, invested $9.9 billion in R&D, but at this point fewer than 5 percent of the 1,300 biotech companies have products on the market. So, as a whole, the industry had a net loss of $5.1 billion.

So how was this funded? It was funded by private investment. I have personally raised almost a quarter of a billion dollars for Aviron's vaccine programs from venture capitalists, from private equity markets, public equity markets, public offerings, and convertible debt.

I can tell you, it has not been easy. Forty-six percent of biotech companies have less than 2 years of cash burn left, even as they move closer into the more expensive clinical trials. A quarter of these companies have less than a year of cash less. So this is fragile, this system that we are hoping is successful.

Our investors require the promise of an appropriate reward for these long development cycles of biotechnology products, and they are exquisitely sensitive to signals from Washington. They are paying attention.

Even the threat of price controls really does have an impact. It is not ideological, it is just the way it works. When I am out there raising money, I always hear that a further concentration of government purchasing power will dry up investment in biotech projects.

My office is in the heart of Silicon Valley. It takes hundreds of millions of dollars, and many years, to build a wafer fab to take us to the next generation of micro processors.

Just imagine how high-tech investors would look at it if the Federal Government suddenly commandeered 40 percent of the market from the next generation of micro processors in terms of their thinking about making these investments. That is a lot of what this so-called Prescription Drug Fairness Act looks like.

I can tell you from personal experience, it was very much more difficult to raise money for Aviron in the midst of the Clinton health care debate earlier in this decade. People were saying, how do we know they are not just going to confiscate it once you succeed?

Increasing seniors' access to prescription drugs through fiscally responsible, decentralized, pluralistic, private market structures—that is a mouthful, but I really think there are solutions out there that can balance the need to keep the innovation going and help us with the access problem.

Thank you very much. I would look forward to discussing that further with you.

[The prepared statement of Dr. Read appears in the appendix.]

The CHAIRMAN. Thank you, Dr. Read.

It is a pleasure to welcome you, Ms. McSteen.

STATEMENT OF MARTHA A. McSTEEN, PRESIDENT, NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE, WASHINGTON, DC

Ms. MCSTEEN. Thank you, Mr. Chairman and members.

I am Martha McSteen, president of the National Committee to Preserve Social Security and Medicare. We are a grass-roots education and advocacy organization, with about 5 million members and supporters across the country.

Mr. Chairman, the National Committee strongly supports prescription drug coverage in the basic Medicare benefit. For our

members and millions of seniors nationwide, the rising cost of prescription drug medications is an ongoing struggle.

The average senior takes 4 prescriptions daily, fills an average of 18 prescriptions a year, and spends approximately three times as much on out-of-pocket health expenses as the under-65 population, largely because more than one-third of seniors have no insurance for outpatient prescription drugs.

Mr. Chairman, in 1965 when Medicare was established, I served as one of the 10 regional administrators for the new program. Congress did not create a drug benefit because the practice of medicine at that time relied primarily on hospital-based and physician-provided care.

Today, modern medicine is increasingly relying on pharmaceuticals. Sixty-four percent of the visits by seniors to their physician result in the prescription of medication. But so long as prescription drugs are available to some but not to all, then this Nation's health system will tragically continue to fail millions of our seniors.

America's seniors also need something done about the cost of prescription drugs. Prices have risen more than 50 percent since 1989, and seniors have little clout in the retail market.

A recent Standard and Poors report documented how drug manufacturers provide large purchasers with sizable discounts on the most popular prescription drugs and make up the lost revenue by increasing the retail price of pharmaceuticals for the private market, where average seniors buy their medications.

Thirty percent of all seniors have annual incomes below $10,000, and the high price of pharmaceuticals is a punishing burden. Seniors like Arnetta Fern Bakner, a National Committee member, a 78-year-old widow from Indiana, is disabled, has endured several surgeries and takes medication for her heart. Her income is $940 a month. After paying for her supplemental health insurance, her medications, her life insurance, her estate taxes, her utilities, she has $15 a month left to cover food and gasoline.

Members like Robert Johnson of Florida, who is 78 and suffers with hypertension, has had quadruple bypass surgery and takes six different drugs prescribed by his cardiologic. His out-of-pocket pharmaceutical costs are more than $2,300 a year, not counting the six vitamins prescribed by his physician, and the $4,928 he pays in premiums for Medigap and private long-term care insurance.

The National Committee members urge Congress to pass legislation to make drugs affordable for seniors and include a drug benefit in the basic Medicare package. The National Committee supports S. 731, the Prescription Drug Fairness Act for Seniors.

This legislation would provide Medicare beneficiaries with purchasing power similar to that of the HMOs, State Medicaid agencies, the Public Health Service, and the Veterans Administration, all of which enjoy bulk discounts.

We believe the establishment of a comprehensive drug benefit, such as Senator Kennedy's S. 841, is essential for the adequate health care of seniors. A basic Medicare drug benefit must be universal. The cost in Medicare overall might be saved and used for a drug benefit by modernizing Medicare's benefit package.

One cost-effective solution that is being tried in the field is making geriatric case managers an integral part of care. Too often, seniors become ill because of preventable circumstances, such as incompatible prescriptions or improper nutrition.

Geriatric case managers can coordinate care across an interdisciplinary team rather than wait until a beneficiary's health deteriorates and requires an expensive intervention.

Let me say, in conclusion, to those who suggest that America cannot afford a drug benefit for all seniors, that Social Security and Medicare already have contributed heavily to the era of deficit reduction and have assisted in today's economic prosperity.

America has the resources, we need the leadership. Medicare should share our current economic prosperity with the addition of a benefit that is in keeping with the modern medical practice. Thank you very much.

[The prepared statement of Ms. McSteen appears in the appendix.]

The CHAIRMAN. Thank you very much, Ms. McSteen.

Let me turn to you, Dr. Mellion. Recently, the New York Times reported that the administration was relying on research that indicated that a dollar increase in pharmaceutical expenditures is associated with a $3.65 reduction in hospital care expenditure. What is the experience of Blue Cross/Blue Shield?

Dr. MELLION. First, may I say that I read that article in the New York Times, and it said "confidential research." So I would like to raise the issue of some research that was not confidential, 4 years ago, published in the Journal of Family Practice. It was an article that showed that the more money you spent on pharmaceuticals for asthma, the less you spent overall on asthma.

But I must say that any piece of research of this nature is a snapshot with a date on it, because the cost of the pharmaceuticals 4 years ago does not reflect what the cost of pharmaceuticals for asthma would be now.

The cost of hospitalization and ER visits has not gone up anywhere near as much as the cost of pharmaceuticals. In our plan, for example, we are paying 50 percent more for pharmaceuticals than we are paying for outpatient visits in all of our care. So, that is a temporal study and it is outdated the minute it is published. The question is, how do you project those kinds of numbers into the future.

The CHAIRMAN. At the same time, you have had an experience of several years. There seems to be some evidence that drugs do save money.

But what is your most recent overall experience; can you comment on that?

Dr. MELLION. Well, in certain diseases, at a high level of intensity, there is no question that drugs save money. But when more expensive drugs are used across the board to people who would do as well with drugs that are not as expensive, that balances it off.

What we have seen is, our overall costs are going up, but the segment that is going up the highest is the cost for pharmaceuticals. We are reaching a point where the savings that we are making on hospitalizations has leveled off.

The CHAIRMAN. Let me turn to you, Mr. Holmer. A couple of people have raised the point that the cost of drugs are substantially higher in this country, say, than Canada or abroad.

Let me point out, for example, I think in today's Washington Post, Robert Cuttner said, "On average, drug prices are between one-third and one-half higher in the United States. American consumers and taxpayers, in effect, subsidize consumers in Europe, while we pay the world's highest drug prices."

Why is that? Is that correct?

Mr. HOLMER. Well, I would need to have a chance to look at the specific numbers. Oftentimes, you find comparisons fail to take into account the discounts or rebates that frequently occur in the United States.

As you know, all European countries have socialized medicine and strict price controls. In some countries, manufacturers steal the product and then produce it without compensation to the inventor. You have got complex factors like exchange rates, and other items.

The CHAIRMAN. Well, let me point out, we had the ladies in the bus who went up to Canada and had this experience.

Mr. HOLMER. Right.

The CHAIRMAN. Why should we be subsidizing the cost of foreign purchases?

Mr. HOLMER. I guess I would look at it this way. There may be circumstances where products are lower in Canada because of price controls that are imposed in Canada. But I would want you to ask a very important question, both with respect to Canada and Europe: name the last medicine that you know of that was discovered and developed in Canada?

The CHAIRMAN. We are getting to a different question, now. I agree and applaud the fact that U.S. industry is the most innovative, most inventive.

Mr. HOLMER. Right.

The CHAIRMAN. At the same time, it does bother me that there is apparently some evidence that more is being paid by American consumers than they pay abroad. It sort of sounds to me like the Japanese practice in other industries where they charge higher prices at home to promote trade abroad.

Mr. HOLMER. If I could respond on one other aspect of this, which I think is enormously important as you try to address this overall question. What I include in my testimony are references from the Boston Consulting Group, who very recently did a study in this overall area.

What they found, and they looked particularly at European, where they imposed price controls in Europe, number one, they do not succeed in keeping pharmaceutical spending down. The price controls generally do not work.

Second, if you are successful in squeezing the balloon with respect to pharmaceutical expenditures, it pops out someplace else with respect to emergency room referrals, or hospitalizations, or other kinds of things.

Third, patients are hurt by price controls. On average, after a drug is approved in any country, it takes about 5 to 6 times longer for that drug to get to market in the U.K. and in other countries

than it does in the United States. It takes a longer time for generics to be able to come on to the market and to have price reductions in those countries compared with the United States.

We do have a form of price control in this country, but it is through the generic competition that works quite effectively. I know you want to move on. I have an important additional point to make in that respect, but I will defer that until later.

The CHAIRMAN. We welcome any of you to supply any additional information as part of the record.

I will call on you, briefly, Dr. Read, because I want to ask Ms. McSteen a question, too. Please, Dr. Read?

Dr. READ. Just briefly. I have been puzzled too by this. I think the phenomenon is real, that we do pay higher prices here in this country, although you can criticize specific studies. I think it is because these other countries are getting a free ride.

The United States is a vast exporter of innovative technology. The numbers and the research really do support that the vast majority of new prescription medicines are coming out of U.S.-based and U.S.-sponsored research.

It is partially because of our support for NIH, and partially because of the healthy market, the rewards for innovators in this area. It does not seem fair. Our choices, though, are not very attractive. We can cut ourselves back and have less medicines for everybody, or we can find some other way to work with these other governments so that there is less of a free rider phenomenon going on.

The CHAIRMAN. I think it is a matter of real concern and something that we will want to obtain additional information on.

Ms. MCSTEEN, LET ME ASK YOU THIS. I know and understand that you very strongly believe in full coverage for all senior citizens. But assuming that it is going to be phased in and not all at once, do you have any thoughts or recommendations of how it should be phased in?

Ms. MCSTEEN. Well, of course, that is a very difficult question and what we are all seeking an answer to. We would like very much to see us move in the direction of availability and accessibility for all seniors because, as we have heard this morning in testimony, certainly savings can be gained in the long run if an individual has access to the correct drugs.

I think what this is committee is doing, and Senator Breaux's legislation, and Kennedy, and Allen, are steps in the right direction, that we must do something to recognize the way physicians are treating patients these days is far different from 1965.

The CHAIRMAN. There is certainly no question about that. I could not agree more with you.

Senator Moynihan?

Senator MOYNIHAN. A very few remarks. To say, first of all, thank you to the panel for wonderfully illuminating a number of issues.

Can I say, Mr. Chairman, and this is no effort to curry more than the normal favor, you did set an example by using the term "cost of drugs" correctly. We have had that phrase used repeatedly all morning, meaning the total outlay for drugs. That is a different

thing altogether than the cost of aspirin, the price per pill, as it were.

I do not know what the movement there has been, but I expect it is rational if there is enough competition. I do not know that the idea that there are drugs that are imitated by competitors is a bad idea, because it breaks up monopolies and makes for markets. We are talking about markets here. But not entirely.

I think it was important to keep in mind that, and Dr. Read indicated, an awful lot of the basic research takes place in medical schools, funded by the NIH and others. That is what economists call a public good. It will not be provided by markets. If you have markets working, as increasing we do, you have to look to that.

The matter of the exported products being sold at below the price here, that may be a rational business practice. I do not know. But it strikes me, I can see why it might be. I think we need to get Secretary-designate Summers up here to tell us; he would know. Or Alan Greenspan.

But I would like to say that we are seeing the effects already. The number of hospitals beds is down pretty sharply from 1990, having grown from 1950. The occupancy rate is now 62 percent, which I should think is an inefficient rate, is it not? The number of hospitals is down, in 1990, from 5,420, now to 5,082. That is a significant decline. But these rationalities are working themselves out, I think, very well.

What I would like to assure the panel, and Dr. Mellion and Dr. Read, perhaps, particularly, is that we are aware of the problems of price controls. You mentioned your experience in 1994. Well, that bill came to this committee.

Contrary to many different impressions, it is the Finance Committee that handles health legislation. We were very troubled by the price control provisions and we left them out of a bill we reported, on a bipartisan basis, from this committee, which was rejected as inadequate at the time. People would kill for it today, but that is life in politics.

I can say to you, I think it is fair that price controls are something we know to watch because we have seen the efficacy of competition, of extraordinary benefits. Again, thank all of you for using the word medicine. Medicine is a good, old-fashioned word.

Mr. Holmer?

Mr. HOLMER. Yes, Senator. Just, one, thank you for making clear that it is costs or expenditures that have gone up so much. The price increases over the course of the last several years have ranged in like the 2 to 3 percent range. It is the volume or the change in the mix to the new or more innovative medicines.

To go precisely to your point, I had my staff bring a chart. This shows the percent change, annual change, in U.S. research and development by the research-based pharmaceutical industry.

Senator MOYNIHAN. You get private firms.

Mr. HOLMER. Private firms, correct. The percent change, going from 1980 to 1999. It goes to the point that Dr. Read was describing, which is, you see numbers there, and normally those are double-digit numbers. This year, the percentage increase is 14 percent. If you look at what happened in 1994 and 1995, there is a dramatic drop-off.

I wonder what happened about that time, Senator, that might have caused the companies to decide that they had to ratchet back with respect to the research and development? It was the effect of the last time this Congress pursued the issue of price controls. We hope you will keep that in mind as you proceed with respect to your deliberations.

Senator MOYNIHAN. I hope you will let us have a copy of that bar chart.

Mr. HOLMER. Absolutely. We would be pleased. You can have it now, actually. [Laughter.]

Senator MOYNIHAN. Thank you. Thank you very much.

Mr. HOLMER. You bet.

The CHAIRMAN. Senator Breaux?

Senator BREAUX. Thank you very much, Mr. Chairman. Thank all the panel.

Ms. McSteen, I moved over here so I could see you better. I want to have a dialogue with you. And thank all the other panel members for their presentations and look forward to working with you.

Let me start, Ms. McSteen, by saying that I have the utmost personal respect for you and, I might add, also for your husband, who is a world-class pediatric eye surgeon. The work that he has done is magnificent. But I have lost all respect for your committee, and I want to talk to you about that.

The letter that you have sent out under your name to, I do not know, maybe 5 million members, I think, follows the rule of professional fundraisers in Washington when they tell you, when you do a fundraising letter, the first thing you do is make it as outrageous as you possibly can, second, scare the hell out of the people that you send it to, and, finally, ask for money.

If that is the criteria, you all have done very well in each category. Number one, you start off by saying that the product of the National Commission was nothing more than a government voucher. Second, you further scare the hell out of them by saying that there is no guarantee that they will have any benefits. Third, the final kicker, is you ask for money, and you ask for money, and you ask for money.

On page 3, "Your generous special donation to derail this plan is needed. We also need as generous a donation as you can afford. Send your petition with your special donation as soon as possible. Make a special donation today. Please endorse this petition and enclose with it as generous an emergency donation as you can afford."

The last one, "Boost our grass-roots effort by including an emergency contribution. Your contribution of $15, or even $23." And I am not sure why the odd number $23.

Further on, "Our suggested contribution amounts or anything you can give will help more than you know. Please decide the most you can afford and enclose your check." Finally, "Enclose your petition along with your contribution of $23, or at least $15, in the envelope provided."

I mean, this is classic. It meets all of the criteria by the professional fundraisers. I take it you did not really draft this, did you?

Ms. MCSTEEN. Senator Breaux, I regret very much—we have worked together through the years and tried very hard to be very supportive of the issues. We are a grass roots organization. A mem-

ber pays $10 a year and all of our mail does not ask for money. But, when there is a special issue, we ask for money. The average contribution per member is $11.

Senator BREAUX. I appreciate that. But did you really draft this?

Ms. MCSTEEN. No.

Senator BREAUX. All right. I am glad you said that, because I would really be disappointed.

Let me ask you some content about the letter itself. First of all, the biggest criticism, you say that what the Commission reported was nothing more than a voucher. The Commission's recommendation in the area is exactly the same way that the Federal Employees Health Benefit Plan works, whereby, myself, Senator Roth, and 10 million other Federal employees, each year, get a whole array of choices and we pick one.

The Federal Government pays 75 percent of the costs of the plan, we pay the rest. That is the same recommendation that we had in the National Commission. Tell me how the Federal Employees Health Benefit Program is a voucher system.

Ms. MCSTEEN. Well, I do not think that is my responsibility, to try to dissect the Federal employees.

Senator BREAUX. All right. Then tell me how the National Commission, which you refer to in your letter, is a voucher system when the Federal Government pays the company directly?

Ms. MCSTEEN. That is really a matter of semantics. A voucher does not mean that it is an open ticket to buy what is needed. You can call it a blank check or you can call it something else. But what we are saying——

Senator BREAUX. So when the government pays the cost of the plan, 75 percent of it, your organization considers that a voucher?

Ms. MCSTEEN. As I am saying, voucher is a word that can be interpreted in different ways. You apparently have interpreted it in that way. But I must insist that we are an organization that represents its membership.

Senator BREAUX. I understand. I understand. I just want to find out the content of the letter, because I disagree vehemently with the characterization.

The second point you make, is that there is no guarantee of benefits. The National Commission said that the beneficiaries would be guaranteed the same, identical benefit plan that Medicare currently gives to the beneficiaries. How is that not a guarantee?

Ms. MCSTEEN. There is no assurance that that would happen because the amount, the rate, the charge could be changed at any time in the future by the Medicare Commission, if that is established.

Senator BREAUX. Is that not exactly the same way the Medicare is today? We could change it tomorrow, could we not?

Ms. MCSTEEN. Well, it has not happened in that respect.

Senator BREAUX. Let me make one final point. I think that this is an incredibly difficult problem, and people have to be positive in contributing to solving the problem.

I would suggest that, when an organization that purports to other organizations that are a representative of seniors, use this as a massive fundraising effort, that is unfortunate.

The Committee to Preserve Social Security and Medicare, I think, should now be called the Committee to Preserve Itself, and that is extremely unfortunate because you have the ability to do a great deal of good. This letter, unfortunately, does not represent that.

Ms. MCSTEEN. Well, I regret that you feel that way, because certainly we have used our informational communication very successfully to your constituents, as well as others. We can stand behind what we are saying. We also recognize that there are many other people, members of the Congress and also other organizations, who would support what we have said already.

Senator BREAUX. Well, you have used this as a fundraising tool and scaring the bejesus out of the seniors. I do not mind you disagreeing. I would like you to be accurate when you disagree. But you have followed the classic recommendation of Washington professional fundraisers: make it as outrageous as you possibly can, scare the hell out of them, and then ask them for money. That is what the difference is.

Ms. MCSTEEN. You know, I am very disappointed that you have that narrow of perspective, because we have been using direct mail for some time. Our members like to have in print, and in large print, and to discuss these issues at home. We have supported you. We did use your name because your name is in the bill. If you regret that, I am sorry.

Senator BREAUX. I do not mind you using the name, Ms. McSteen. I mind you being inaccurate in characterizing it as being a voucher system, or it does not guarantee benefits. That is the difference. You can use my name. I am proud of the product that we tried to produce.

Ms. MCSTEEN. Well, you are just exaggerating one person's conception of what voucher means. We are both thinking the same thing, that we are trying to reach out to our membership and individuals across the country to help solve this problem.

The CHAIRMAN. Your time is up.

I will ask one question of Mr. Sanders, because you do have a unique perspective in that you worked as an executive in the Medicare program, as well as in the private sector.

As we explore the possibility of a pharmaceutical benefit for the Medicare program, which I think is very important, what are the key lessons from the experience with FEHBP in the private sector? Are there other benefit and design issues we need to be especially careful about? For instance, what is the significance of co-payment versus co-insurance?

Mr. SANDERS. I think my experience with Medicare and my experience in the private sector with the Federal Employees Health Benefits suggests if you are going to take advantage of the savings that pharmacy benefit managers and managed care plans now produce, that is part of the issue we talk about with prices. We are actually producing drugs that are 20 or 25 percent less than list prices in what we negotiate.

If you are going to do that, it is going to work a lot better in a program that is more styled like the Federal Employees Health Benefit Program than a highly regulatory, prescriptive program

like the Medicare program. It does not have to be that way, that is just the experience.

So in our experience, we support the structure that was proposed by the bipartisan commission, with something where there is an advisory board or something that is distanced a little bit that allows competition to occur, or something more like the Federal Employees Health Benefit Program. We think that that will produce a higher quality, lower cost benefit for Medicare seniors.

You mentioned co-insurance versus co-payments, in particular. I think that it may not be as big as some of the other issues you are struggling with, but it is very important as a second-tier issue.

Medicare seniors, all beneficiaries, prefer and find co-payments—that is, a flat co-payment—for drugs easier to use and easier to understand. Our research suggests that.

However, coinsurance has automatic indexing to the cost of drugs. You are asking people to pay 25 percent. Then if the drug is higher priced, they pay 25 percent of that higher-priced drug.

If you are going to do a co-payment that puts the right cost control and the right incentives in, you are going to actually have to have a fairly complicated co-payment structure. So it is a balancing act and it is something that is an important design feature of how you set up the Medicare program.

The CHAIRMAN. Mr. Holmer?

Mr. HOLMER. Just very briefly. I would like to associate myself completely with what Mr. Sanders has just said in terms of the preference of the FEHBP-like plan as opposed to a giant new government program. The other key aspect of that, is if you do it that way it will not stifle innovation.

I would like to be able to insert in the record just an article from the Wall Street Journal in April which said, "'European drug companies will provide fewer top sellers,' says research ground."

It says, "The European pharmaceutical companies, which 10 years ago dominated the drug industry, will supply only 3 of the world's top-selling 25 drugs by the year 2002." It says that, "By 2002, no fewer than 20 of the world's top 25 best-selling drugs will be marketed by U.S. companies."

What we need to be able to do, is to maintain the kind of kind of environment we have in the United States that nurtures biomedical innovation, and at the same time provide expanded drug coverage for seniors. That is why we are so encouraged by the work of the Medicare Commission.

The CHAIRMAN. Yes, Dr. Read.

Mr. SANDERS. Just a quick point. Going back to something that came up earlier related to me too drugs, these new players, who are able to evaluate the cost effectiveness of drugs in the context of how they substitute for medical procedures, surgery, and the kind of things that we are looking for, exercise a great deal of discipline over look-alike drugs. That is one of the places where this pricing discipline is working.

I think there is tremendous reason for optimism, that we do not just have to say, well, we are just the captives of whatever people want to charge if we want innovation.

There are market-based mechanisms that can operate, and they are going to happen the best in the context of an overall reform of

Medicare, I believe. But if there are things that we are going to do in the shorter term, then we really need to focus them where the need is the greatest.

The CHAIRMAN. Well, the hour is growing late. I just want to say that we are all very proud of the innovativeness, of the inventiveness, of the American industry.

It is obviously critically important that we continue to have an environment that encourages that. We also want to make sure that there is access for everyone at costs they can afford.

So, we would welcome any further suggestions or recommendations you have to make. We appreciate your being here today. I think it is critically important that we reform Medicare, and do it in such a fashion that we take advantage of the tremendous progress that has been made in the area of drugs.

Thank you very much. The committee is in recess.

[Whereupon, at 12:37 p.m., the hearing was concluded.]

APPENDIX

Additional Material Submitted for the Record

Prepared Statement of Kevin W. Concannon

Good morning. My name is Kevin W. Concannon. I am the Commissioner of the Maine Department of Human Services. In Maine, our Department administers the Medicaid Program, the health insurance program for low income and increasingly for many middle income elderly persons and the state's Drugs for Maine's Elderly Program in conjunction with the Maine State Treasurer's office. In a state of 1,200,000 people, the Maine Medicaid Program serves 164,000 Mainers on any given day and close to 200,000 Maine residents over the course of a year. While low income elderly and disabled persons represent about 25% of the caseload, their health care needs translate into a much higher costs and they represent approximately 70% of the cost of the Medicaid Program. Within Maine's Medicaid Program, which has an annual budget of $1 Billion, 200 Million the cost of drugs for Medicaid patients amounts to $140 million per year in state and federal funds. As the Committee Members are aware, drug benefits are optional programs under the Medicaid scheme but virtually all 50 states avail themselves of the option to provide drugs. As the CEO of the state health agency in Maine and formerly in Oregon, I can state unequivocally that we believe the drug benefits are among the most highly efficacious components of our health care system. In Maine, for example, some 57,000 elderly depend on the drug benefit daily either through the State's Medicaid Program or through our Drugs for the Elderly Program. And for those disabled persons in our program who are age 65 or older, on average they have more than 6 medications per day that they're reliant on for their health. Maine has a state of the art Point Of Sale information technology system—that is an online computer information system connected to virtually every drug store in our state which provides instant both access information, eligibility, payments, drug utilization information and has a software program designed to identify potential adverse drug interactions. This system provides immediate access not only to our pharmacy consultant but our medical director for purposes of monitoring, tracking and improving the use of medications on behalf of our patients.

Of serious concern to State Medicaid Programs is the experience we've had in recent years of virtually double-digit increases each year in the cost of the drug benefits under Medicaid. These increases are due to new drugs coming on line which are invariably more costly, the increasing cost of generic drugs, the direct marketing to consumers by the drug manufacturing companies and the manufacture of look-alike drugs that have the effect of extending the patent on individual drugs which in the past whose patent may have run out.

The Medicaid Program in our state contains costs by relying on cost caps, the drug rebate program, the monitoring of our point of sale information systems, the use of prior authorization, the express preference for the use of generics and our developing and increasing focus on prescribing practices by physicians.

We also administer the Drugs for the Elderly Program. Maine, twenty years ago, started a limited drug benefit for elderly persons and disabled persons whose incomes were above the Medicaid eligibility. There are now some fifteen states which have drugs for elderly programs of varying scope for people above Medicaid eligibility. It was expanded in 1993-1998 and with the recently ended Maine legislative session in 1999. Currently people above Medicaid income eligibility up to 134% of the poverty level are eligible for the Maine Drugs for the Elderly Program. By October 1, this program will increase to cover disabled persons over age 19 and elderly up to 185% of poverty. The core of the Drugs to the Elderly Program in Maine provides drugs for 12 common costly conditions affecting the elderly. These conditions

are diabetes, cardiac conditions, high blood pressure, arthritis, anti coagulation, chronic obstructive lung disease, high cholesterol, osteoporosis, thyroid diseases, glaucoma, Parkinson's disease, multiple sclerosis and Lou Gherig type Diseases. Access to the program is administered by the State Taxation Department that automatically sends notice of eligibility to persons when they file their taxes if their age and their income falls under 134%, soon to be 185%, of the poverty level based on family size. Access to the program is through a simplified application. We also provide these applications through all of the offices of the Department of Human Services. Persons receive their drugs through local drug stores as they would in the private sector or if they were a Medicaid patient. We rely on the same point of sale information system that provides us instantaneous service analysis in our Medicaid system. In Maine, the DEL program currently covers some 22,000 lives. We rely upon the drug rebate program through drug manufacturers for a significant portion of the income needed to run the program ($7.7 million per year). The elderly consumer in our program pays a 20% co-pay for the cost of his or her drugs. The drugs are provided to the person at the Medicaid cost, which in Maine is the Average Wholesale Price (AWP) minus 10%. The expansion this year reflects work on a bipartisan basis between the Republicans and Democrats and our Independent Governor. It should be noted as well for the Committee that both our Senator Olympia Snowe and one of our Congressmen, Congressman Tom Allen, have introduced separate legislation in their respective branches of Congress to provide a drug benefit for Medicare recipients. We see daily and hear daily from people who are struggling with the enormous burden of increasing exorbitant health care drug costs and we applaud the efforts of our Senator and Congressman and hope that their efforts will result in enacted legislation in the future.

In the meantime I might say to this Committee that on behalf of states that for purposes of improving access to drugs for the elderly, Medicaid programs should be given more flexibility similar to that which has been authorized under OBRA 90 for contracted pharmacy benefits and the states should be given the opportunity to limit, for example, lifestyle enhancing drugs. Also, there should be incentives to the states for actively managing or rewarding good drug prescribing practices. I think this is particularly important as physicians report to me the pressures they feel from patients coming to them who have been subjected to cable TV advertising, advertising in the newspapers, magazines, on the internet, advertising at every turn urging them to talk to their physician to secure a specific drug. This undoubtedly has had an impact on prescriptions and prescribing practices. Also I might note that it is our belief that the Medicare Program would benefit in terms of purchasing practices from the same approach that is used typically in Medicaid across the country. It is my understanding that Medicare pays the sticker price or pays Average Wholesale Price for drugs across the country. There is no state that follows that practice fortunately in its Medicaid Program. On average, states pay the average wholesale price minus 10% and beyond that receive a drug rebate from the companies based on the prices they extend to their largest customers. It would seem to me that Congress should give equal consideration to that approach for the Medicare program as it would enable further coverage of many lives and would be using market forces and purchasing power to secure a reasonable discount to Medicare as one of the largest purchasers of drugs in the country.

I would be happy to respond to questions from the Committee and appreciate the opportunity to be here today.

United States General Accounting Office

GAO

Testimony

Before the Committee on Finance, U.S. Senate

For Release on Delivery
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MEDICARE

Considerations for Adding a Prescription Drug Benefit

Statement of Laura A. Dummit, Associate Director
Health Financing and Public Health Issues
Health, Education, and Human Services Division

GAO/T-HEHS-99-153

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you consider a prescription drug benefit for Medicare beneficiaries. Over the past several months, this Committee has held a series of hearings on Medicare reform issues to determine the nature and extent of changes needed to modernize the program and control its impact on the federal budget. These discussions come at an important juncture in the program's history—the Congress passed landmark legislation in the Balanced Budget Act of 1997 (BBA) that has the potential to improve the financial underpinnings of the program. Yet, more work remains to ensure Medicare's continued financial viability. Budget projections show health care consuming ever-larger shares of the federal dollar, thus threatening to crowd out funding for other valued government programs and activities. At the same time, many believe that Medicare's current benefit structure should be updated to include a prescription drug benefit.

Studies suggest that broadening Medicare coverage to include prescription drugs could add between 7.2 and 10 percent to Medicare costs. Such an expansion would occur at a time when Medicare's rolls are growing and are projected to increase rapidly with the aging of the baby boom generation and during a time of major technological advances in medicine and biotechnology. Currently, some Medicare beneficiaries face a significant financial burden for outpatient prescription drugs. The policy dilemma before you today is that, on the one hand, Medicare's lack of a prescription drug benefit may impede access to certain treatment advances, whereas on the other, the cost implications of including a prescription drug benefit will be substantial. These additional costs would serve to erode the projected financial condition of the Medicare program, which, according to the Medicare trustees, is already unsustainable in its present form.

My remarks today will focus on the factors contributing to the growth in prescription drug spending for both the general population and Medicare beneficiaries and efforts to control that growth. I will also discuss benefit design and implementation issues to be considered in deliberations about adding a new prescription drug benefit. My comments are based on analyses of recent data and our body of completed work on prescription drugs.

In summary, proposals to add prescription drug coverage to Medicare's benefits come during a period of rapid growth in national spending for pharmaceuticals and transformations in the prescription drug market. Increased coverage of drugs by health plans and insurers, advances in drug treatments, and aggressive marketing have spurred the growth in the use of pharmaceuticals, while the use of formularies, pharmacy benefit managers, and generic substitutions as cost control approaches have dramatically changed the nature of the market in which prescription drugs are purchased.

What remains unchanged since 1965, however, is the absence of coverage for outpatient prescription drugs by traditional Medicare. A third of the Medicare population lacks the supplemental drug coverage provided to most beneficiaries through employer-sponsored plans, managed care organizations, Medicaid, or Medigap insurance. Moreover, high

drug utilization among the Medicare population translates into a potentially daunting financial burden.

The implications of adding prescription drug coverage to Medicare's benefit package depend on the choices made regarding details such as its scope and financing. Its design and implementation will also shape the impact of this benefit on beneficiaries, Medicare spending, and the pharmaceutical market. Recent experience provides at least two approaches for implementing a drug benefit. One would involve the Medicare program obtaining price discounts from manufacturers. Such an arrangement could be modeled after Medicaid's drug rebate program. While the discounts in aggregate would likely be substantial, this approach lacks the flexibility to achieve the greatest control over spending. It cannot effectively influence or steer utilization because it does not include incentives that would encourage beneficiaries to make cost-conscious decisions. The second approach would draw from private sector experience in negotiating price discounts from manufacturers in exchange for shifting market share. Some plans and insurers employ pharmacy benefit managers (PBM) to manage their drug benefits, including claims processing, negotiating with manufacturers, establishing lists of drug products that are preferred because of price or efficacy, and developing beneficiary incentive approaches to control spending and use. Applying these techniques to the Medicare program, however, would be difficult due to its size, the need for transparency in its actions, and the imperative for equity for its beneficiaries.

MANY FACTORS HAVE SPURRED PRESCRIPTION DRUG SPENDING AND FOSTERED MARKET CHANGES

Extensive research and development over the past 10 years have led to the introduction of new prescription drug therapies and improvements over existing therapies that, in some instances, have replaced other health care interventions. The growing importance of prescription drugs as part of health care has made the inclusion of drug benefits an attractive policy feature to consumers with a choice among health insurance products. Most commercial private health insurance products, Medicare+Choice[1] plans, and all Medicaid programs provide their beneficiaries with an outpatient prescription drug benefit. Health plans have found that including prescription drugs as a covered benefit helps attract members and is valuable to their beneficiaries. Prescription drug expenditures have outpaced other components of health care spending in recent years due to several factors. At the same time, the use of new approaches to dampen these expenditures is reshaping the prescription drug market.

Rise in Prescription Drug Spending

Over the past 5 years, prescription drug expenditures have grown significantly, both in total and as a share of all health expenditures. Prescription drug spending grew, on average, from 1992 to 1997 by 11 percent a year compared with a 5 percent average

[1] As an alternative to traditional Medicare fee-for-service, beneficiaries in Medicare+Choice plans (formerly Medicare risk health maintenance organizations) obtain all their services through a managed care organization and Medicare makes a monthly capitation payment to the plan on their behalf.

growth rate for health expenditures overall. (See table 1.) Drug spending during that same period also consumed a larger share of total health care spending—rising from 5.6 percent to 7.2 percent.

Table 1: National Expenditures on Prescription Drugs, 1992-1997

Year	Prescription Drug Expenditures (in millions)	Annual Growth in Prescription Drug Expenditures (percent)	Annual Growth in All Health Care Expenditures (percent)
1997	$78,888	14	5
1996	$69,111	13	5
1995	$61,060	11	5
1994	$55,189	9	5
1993	$50,632	9	7
1992	$46,598	11	9
Average Annual Growth, 1992–1997		11	5

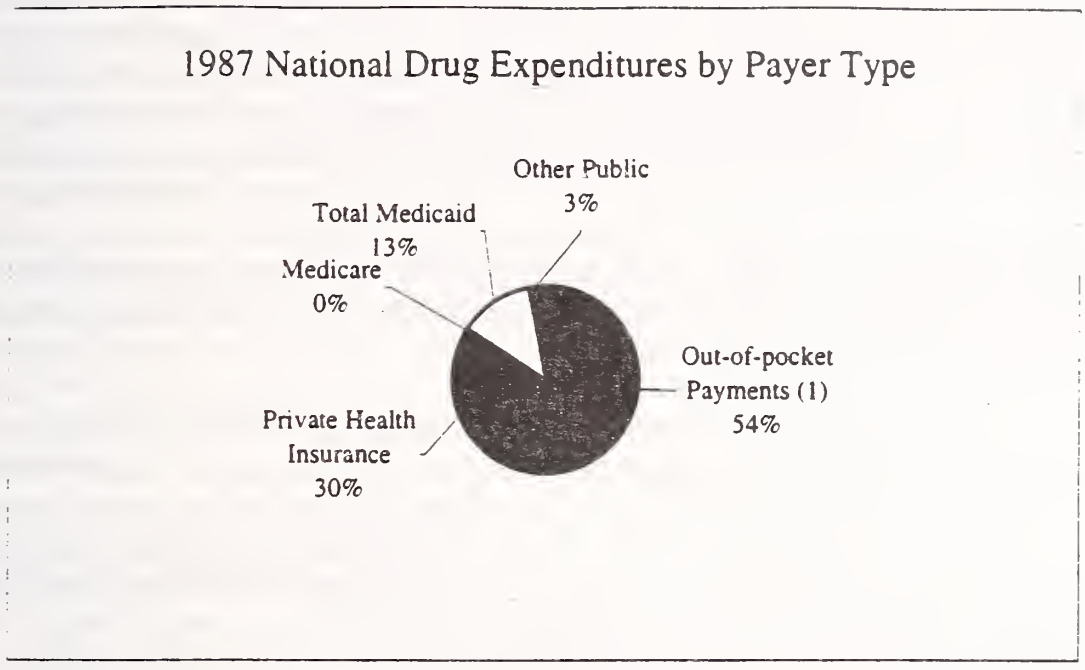
Source: Health Care Financing Administration (HCFA), Office of the Actuary.

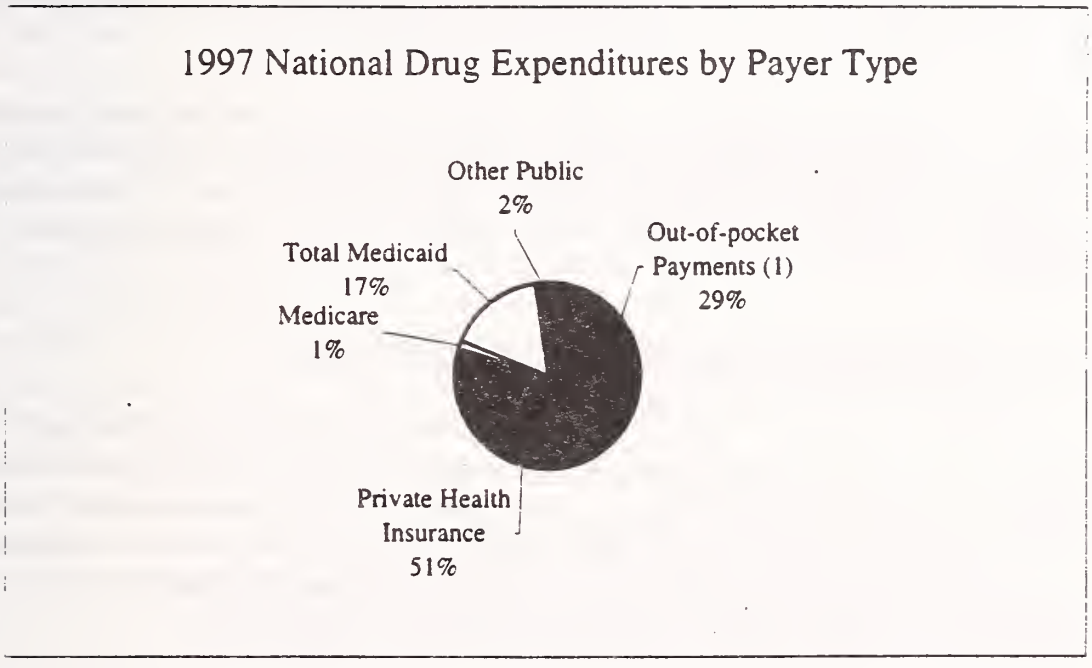
While total drug expenditures depend both on the prices paid and the volume used, the recent spending increases appear to have more to do with stepped up volume than price. A precise determination of how much is due to volume versus price increases is not possible since only data on the retail pharmaceutical prices are widely available. The actual prices paid are often lower than retail levels, as insurers, PBMs, and other purchasers negotiate significant discounts from manufacturers and other suppliers. Market changes in recent years have likely altered the size of those discounts.

Several factors have contributed to increased prescription drug use and the resulting spending increases: namely, more individuals have third-party drug coverage, new drug therapies have been introduced into the market, and manufacturers have marketed drugs more aggressively through advertising directly to consumers.

The increase in private insurance coverage for prescription drugs is a likely factor accounting for the rise in utilization. In the decade between 1987 and 1997, the share of prescription drug expenditures paid by private health insurers rose from almost a third to more than half. (See fig. 1.) The development of new, more expensive drug therapies—including new drugs that replace old drugs and new drugs that treat disease more effectively—also contributed to the drug spending growth. The average number of new drugs entering the market each year has grown from 24 at the beginning of the 1990s to 33 now. Similarly, biotechnology advances and a growing knowledge of the human immune system are significantly shaping the discovery, design, and production of drugs. Advertising pitched to the lay consumer has also likely upped consumers' use of prescription drugs. Between March 1998 and March 1999, industry spending on advertising grew 16 percent, to $1.5 billion.

Figure 1. Comparison of National Drug Expenditures, 1987 and 1997





(1) Out-of-pocket expenditures include direct spending by consumers for all health care goods and services, such as coinsurance, deductibles, and any amounts not covered by insurance. Out-of-pocket premiums paid by individuals are not counted here.

Source: Health Care Financing Administration, Office of the Actuary

Current Medicare Beneficiary Drug Coverage

Prescription drugs are an important component of medical care for the elderly because of the greater prevalence of chronic and other health conditions associated with aging. In 1995, Medicare beneficiaries had on average more than 18 prescriptions filled. This varies substantially across beneficiaries, however, reflecting the presence of chronic and other conditions that respond to drug treatment and also financial considerations such as third-party prescription drug coverage. In 1995, annual drug costs were $600 for the elderly, compared to just over $140 for the nonelderly population. For some, spending is considerably higher. In 1999, an estimated 20 percent of Medicare beneficiaries will have total drug costs of $1,500 or more—a substantial sum for those lacking some form of insurance to subsidize the purchase.

This financial burden is due, in part, to gaps in insurance coverage for prescription drugs. One third of the Medicare population lacks drug coverage altogether. Those with third-party protections often face deductibles, cost sharing, or limits on total benefit payments. The vast majority of the approximately 17 percent of Medicare beneficiaries enrolled in a Medicare+Choice plan have drug coverage, as do retirees who have employer-sponsored insurance. All beneficiaries who are enrolled in Medicaid receive drug coverage. Other beneficiaries may purchase Medigap policies that provide drug coverage, although Medigap policies involve significant cost sharing, impose annual limits, may contain significant exclusions, and can be expensive. A Medigap policy with drug coverage can cost $1,500 more per year than an otherwise comparable policy.

Medicare beneficiaries with drug coverage use more prescription drugs and have higher overall drug expenditures than those without drug coverage. This may be because beneficiaries with higher prescription drug needs may be more likely to obtain third-party protections. Alternatively, the lack of coverage for some may inhibit appropriate drug utilization.

Cost Control Approaches Reshaping Pharmaceutical Market

During this period of growth in the volume of prescription drugs used, third-party payers, which have been the primary purchasers, have pursued various approaches to controlling spending. These efforts have initiated a transformation of the pharmaceutical market. A world in which insured individuals purchase drugs at retail pharmacies at retail prices and then seek reimbursement is giving way to third-party payers influencing which drug is purchased, how much is paid for a drug, and where it is purchased.

A common technique to manage pharmacy care and control costs is to use a formulary. A formulary is a list of prescription drugs, grouped by therapeutic class, that a health plan or insurer prefers and may encourage to be prescribed for its enrollees. Decisions about which drugs to include on a formulary are based on their medical value and their price. Both inclusion of a drug on a formulary and its cost can affect how frequently it is prescribed and purchased and, therefore, can affect its market share.

Formularies can be open, incentive-based, or closed. Open formularies are often referred to as "voluntary" because enrollees are not penalized if their physicians prescribe nonformulary drugs. Incentive-based formularies generally offer enrollees lower copayments for the preferred formulary or generic drugs. Incentive-based or managed formularies are becoming more popular because they combine flexibility and greater cost-control features than open formularies. A closed formulary limits insurance coverage to formulary drugs only and requires enrollees to pay the full cost of nonformulary drugs prescribed by their physician.

Many health plans or insurers also contract with a PBM to administer and manage their prescription drug benefit. PBMs offer a range of services, including prescription claims processing, mail-service pharmacy, formulary development and management, pharmacy network development, generic substitution incentives, and drug utilization review. PBMs have successfully negotiated discounts and rebates on prescription drugs with manufacturers.

ISSUES TO CONSIDER IN BENEFIT DESIGN AND ADMINISTRATION

Policymakers considering proposals for including a prescription drug benefit in the Medicare program are facing a myriad of options. Assessing the merits of whether and how to implement these reforms will depend, in large measure, on whom the benefit covers and how it is financed. In such an assessment, it may be appropriate to recall the criteria that the Comptroller General enunciated before this Committee in testimony on March 10. These criteria could guide deliberations on expanding coverage to include prescription drugs: (1) affordability--a benefit should be evaluated in terms of its impact on the sustainability of program expenditures for the long term; (2) equity--a benefit should be fair across groups of beneficiaries and to providers; (3) adequacy--a benefit should foster cost-effective and clinically meaningful innovations, furthering Medicare's tradition of technology development; (4) feasibility--a benefit should incorporate such administrative essentials as implementation and monitoring techniques; and (5) acceptance--a benefit should account for the need to educate beneficiary and provider communities about its costs and the realities of trade-offs required when significant policy changes occur.

Although the Congress will likely examine a number of alternative benefit designs and administrative options, I would like to briefly discuss two approaches that may be considered. One would be similar to how drug benefits are provided in state Medicaid programs, which rely on federal authority to lower drug prices through rebates paid by drug manufacturers to control spending. The other would be modeled after approaches adopted by private sector health plans in which PBMs are typically used to administer various techniques to control pharmacy benefit costs. Each approach has some advantages and disadvantages.

Medicaid Programs Rely on Discounts, Limited Utilization Controls

Before the enactment of the Medicaid drug rebate program as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA), state Medicaid programs paid close to retail prices for outpatient drugs. As the largest government payer for prescription drugs, Medicaid drug expenditures comprised about 13 percent of the domestic pharmaceutical market. Other purchasers, such as health maintenance organizations (HMO) and hospitals, negotiated discounts with manufacturers and paid considerably less.

The rebate program required drug manufacturers to give state Medicaid programs rebates for outpatient drugs. The rebates were based on the lowest or "best" prices they charged other purchasers. In return for the rebates, state Medicaid programs maintain open formularies that permit reimbursement for all drugs manufactured by pharmaceutical companies that entered into rebate agreements with the Health Care Financing Administration.

After the rebate program's enactment, a number of market changes occurred that affected other purchasers of prescription drugs and the amount of the rebates Medicaid programs received. For example, the prices many large private purchasers, such as HMOs, paid for outpatient drugs increased substantially. Moreover, the lowest prices in the market increased faster than the drugs' average prices as drug manufacturers significantly reduced the price discounts they offered private purchasers. As a result, within 2 years the rebates paid to state Medicaid programs fell to the minimum amount required by OBRA.

Although states have received billions of dollars in rebates from drug manufacturers since the enactment of OBRA 1990, state Medicaid directors have expressed concerns about the rebate program. The principal concern involves OBRA's requirement for open formularies, which limits the utilization controls Medicaid programs can use at a time when prescription drug expenditures are rapidly increasing. Although they can require recipients to obtain prior authorization for particular drugs and impose monthly limits on the number of covered prescriptions, other techniques to steer recipients to less expensive drugs are not available to them. These approaches can add to the administrative burden on state Medicaid programs, lead to purchasing more expensive drugs, and create access problems for certain individuals.

Other Payers Employ Various Techniques to Control Expenditures

Other payers, such as private employer health plans, Medicare+Choice plans, and insurance products for federal employees have taken a different approach to managing their prescription drug benefits. They use formularies and copayments to control drug utilization and obtain better prices by concentrating purchases on selected drugs. In many cases, these plans or insurers retain the services provided by a PBM to implement their pharmacy benefit.

Beneficiary cost sharing has had a central role in attempting to influence drug utilization. Copayments frequently are structured to both influence the choice of a drug and purchasing arrangements. While formulary restrictions can channel purchases to preferred drugs, closed formularies, which provide reimbursement only for preferred drugs, have generated significant consumer dissatisfaction. As a result, many plans link their cost sharing requirements and formulary lists. The fastest growing trend today is to maintain an open formulary in which all drugs receive some coverage, with beneficiaries paying different levels of cost sharing for different drugs—typically a smaller copayment for generic drugs, a larger one for preferred drugs, and an even larger one for all other drugs. Reducing the required copayments may also encourage enrollees using maintenance drugs for chronic conditions to use particular suppliers, like a mail order pharmacy.

Plans and insurers have turned to PBMs for their expertise in establishing formulary lists, negotiating prices with manufacturers and suppliers, and processing beneficiary claims, as well as a variety of clinical services, such as drug utilization review. PBMs bring expertise and economies of scale to these tasks that individual plans or insurers may not have. In addition, they often may have more leverage than individual plans in negotiating prices as they combine the purchasing power of multiple purchasers.

Traditional fee-for-service Medicare has generally established administrative prices for services like physician or hospital care and then processed and paid claims with few utilization controls. Adopting some of the techniques used by private plans and insurers might have the potential for better control of costs. However, how to adopt those techniques to deal with the unique characteristics and enormity of the Medicare program raises many questions.

Negotiated or competitively determined prices would be superior to administered prices only if Medicare could employ some of the utilization controls that come from having a formulary and differential beneficiary cost sharing. In this manner, Medicare would be able to negotiate significantly discounted prices by promising to deliver a larger market share for a manufacturers' product. Manufacturers would have no incentive to offer a deep discount if all drugs in a therapeutic class were covered on the same terms. Without a promised share of the Medicare market, these manufacturers may reap greater returns from higher prices and concentrating marketing efforts on physicians and consumers to influence prescribing patterns.

Implementing a formulary and other utilization controls could prove difficult for Medicare. Developing a formulary involves determining which drugs are therapeutically equivalent so that several from each class can be selected as preferred. Plans and PBMs currently make those determinations privately—something that would not be tolerable for Medicare, which must have transparent policies that are determined openly. Given the stakes involved in being selected, one can imagine the intensive efforts to offer input to and scrutinize the selection process.

Medicare may also find it impossible to delegate this task to a PBM or multiple PBMs. A single PBM contractor would likely be subject to the same level of scrutiny as the program. Such scrutiny may compromise the flexibility PBMs have utilized to generate savings. An alternative would be to grant flexibility to multiple PBMs that are responsible only for a share of the market. Contracting with multiple PBMs, though, raises other issues. If each PBM had exclusive responsibility for a geographic area, beneficiaries who need certain drugs could be advantaged or disadvantaged merely because they live in a particular area. If multiple PBMs operated in each area, beneficiaries would choose one to administer their drug benefit. Then, how to inform beneficiaries of the differences in each PBM's policies and the possible need to risk adjust payments to PBMs for differences in health status of beneficiaries using them would become issues.

CONCLUDING OBSERVATIONS

Adding prescription drug coverage to the Medicare program would have a substantial impact on the costs of the program, in addition to the financial well being and health of many of its beneficiaries. The challenge will be in designing and implementing drug coverage to minimize the financial implications for Medicare while maximizing the positive effect of such coverage on Medicare beneficiaries. Most importantly, this substantial benefit reform must be consistent with efforts to ensure the sustainability of the program so that Medicare does not consume an unreasonable share of our productive resources and does not encroach on other public programs or private sector activities. Reconciling these needs will take the kind of leadership and creativity demonstrated by the Congress as it designed and implemented the BBA reforms that extended Medicare's financial viability.

It may also be instructive to return to lessons learned in implementing the BBA reforms. From those efforts, it is clear that major changes to the Medicare program need to be effective, flexible, and steadfast. Effectiveness must include the collection of necessary data to assess impact—separating the transitory from the permanent and the trivial from the important. Flexibility is critical to make changes and refinements when conditions warrant and when actual outcomes differ substantially from the expected ones. Steadfastness is needed when particular interests pit the primacy of their needs against the more global interests of preserving Medicare.

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Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you or other Members of the Committee may have.

GAO CONTACT AND ACKNOWLEDGEMENTS

For future contacts regarding this testimony, please call Laura A. Dummit at (202) 512-7119 or John Hansen at (202) 512-7105. Other individuals who made key contributions include Tricia Spellman, Kathryn Linehan, and Hannah Fein.

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RELATED GAO PRODUCTS

Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness (GAO/HEHS-98-176, June 12, 1998).

Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain (GAO/HEHS-97-60, June 11, 1997).

Pharmacy Benefit Managers: FEHBP Plans Satisfied With Savings and Services, but Retail Pharmacies Have Concerns (GAO/HEHS-97-47, February 21, 1997).

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Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals (GAO/HEHS-94-194FS, August 5, 1994).

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Prescription Drug Prices: Official Index Overstates Producer Price Inflation (GAO/HEHS-95-90, April 28, 1995).

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Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland (GAO/HRD-93-55FS, March 18, 1993).

Prescription Drug Prices: Analysis of Canada's Patented Medicine Prices Review Board (GAO/HRD-93-51, February 17, 1993).

Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions (GAO/HRD-93-43, January 15, 1993).

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Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions (GAO/HRD-91-139, September 18, 1991).

Statement of Michael E. Gluck, Ph.D.

Chairman Roth, Senator Moynihan, distinguished members of the Committee, thank you for inviting me to appear before you today. My name is Michael E. Gluck, and I am Director of Health Policy Studies at the National Academy of Social Insurance. At the request of the Academy's Study Panel on Medicare Financing, I recently completed a report analyzing the costs of potential Medicare outpatient drug coverage and related issues.[1]

The Academy is a nonprofit, nonpartisan research and education organization. Our members, chosen by their peers for their expertise in Social Security, Medicare, and other social insurance or related private programs represent diverse political philosophies, disciplinary training, and professional experiences. We are supported by grants from private foundations. Among our activities, we convene carefully balanced committees of experts to wrestle with policy issues regarding the future of our social insurance programs.

For the past four years, about 60 such experts have come together in five separate committees to work on different aspects of Medicare's long-term future. The Study Panel on Medicare Financing is one of these groups. The panel is evaluating Medicare's financing needs for the next generation and options for meeting those needs. It will release the results of their work later in 1999. Although this Study Panel asked for the analysis I present today, I speak for neither it nor the National Academy of Social Insurance. My comments are my own.

Pharmaceuticals Today

Pharmaceutical therapies, not part of Medicare's original benefit package, have become increasingly important since Medicare was enacted in 1965. A direct result of our investments in biomedical research over the past 30 years, the pace of these scientific advances is accelerating. The Food and Drug Administration approved 62 new drug entities during Medicare's first five years (1966-70), but it approved 149 between 1994 and 1998, an increase of 140 percent. While these discoveries have had important impacts on health care and health, their impact on costs has varied with the drug. In many cases, new drugs substitute for or allow patients to avoid more expensive therapies such as hospitalization and surgery. In other cases, they facilitate new, expensive treatments (as in the use of immunosuppressant drugs for organ transplants). In still other cases, they provide treatment where none existed before, which also increases health care spending.

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[1] Gluck M.E. *A Medicare Prescription Drug Benefit.* Medicare Brief #1. (Washington, DC: National Academy of Social Insurance, April 1999).

Overall, spending on pharmaceuticals has been rising faster than other components of the health care bill. Between 1992 and 1998, spending on pharmaceuticals in the United States almost doubled from $49 billion to $93 billion. In 1999 alone, prescription drug inflation will be between 10 and 20 percent with expectations that similar growth will continue well into the new century.[2] As the role and expense of prescription drugs for Medicare beneficiaries have grown, their absence from Medicare's benefit package has become more visible. With a very few exceptions, Medicare still does not cover drugs used outside of the hospital.

In my testimony today, I would like to do three things. First, I would like to review what we know about the cost of prescription drugs used by Medicare beneficiaries. Second, I would like to discuss the extent to which beneficiaries currently have some insurance coverage to help with those expenses, and how the nature of that insurance is changing. And third, I would like highlight some of the complex issues with which Congress would have to grapple if it sought to add a drug benefit.

Prescription Drug Spending For Medicare Beneficiaries.

Spending on outpatient pharmaceuticals in 1999 is estimated to average $942 per beneficiary, roughly half paid by insurers and half paid out-of-pocket by beneficiaries.[3] Like other health spending, drug expenditures are skewed; a large fraction of beneficiaries spend relatively modest amounts on drugs and a minority spends a great deal (Table 1). About half of beneficiaries have out-of-pocket drug expenditures above $200 a year. About 29 percent (or 9.4 million beneficiaries) have out-of-pocket drug expenses of more than $500, 14 percent (4.5 million beneficiaries) have out-of-pocket expenses of more than $1,000, and 4 percent (1.3 million beneficiaries) have expenses that exceed $2,000.

It is worth noting that these estimates exclude beneficiaries who are enrolled in a Medicare+Choice plan (about 16 percent in 1999). While 95 percent of Medicare+Choice enrollees have some prescription drug coverage through their health

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[2] Associated Press, "Health Insurance Costs on Rise in Northern Nevada," June 14, 1999, http://127.0.0.1:15841/v1?catid=18874883&md5=db78a207f79ccd6669ca7db980b31bd0. Dichter, E., Executive Vice President, PCS Health Systems, Incorporated, presentation on "Drug Trends" to the Council on the Economic Impact of Health System Change conference on Technological Change and the Cost of Health Care, Washington, DC, February 10, 1999. U.S. Congress, Congressional Budget Office, *The Economic and Budget Outlook, 1999-2008* (Washington, DC: U.S. Government Printing Office, January 1999).

[3] Unless otherwise noted, the cost and expenditure estimates in this testimony were done for the Academy by Actuarial Research Corporation using data from the 1995 Medicare Current Beneficiary Survey (MCBS) projected forward to 1999.

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Table 1
Distribution of Medicare Beneficiaries by Outpatient Prescription Drug Spending, 1999[a]

	Total Drug Spending (from all sources)[b]	Out-of-Pocket Drug Spending
No Expenditures	14%	17%
$0.01-$199	19	34
$200-$499	17	21
$500-$999	19	15
$1,000-$1,499	12	7
$1,500-$1,999	7	3
$2,000 or more	13	4
Total Percent of Beneficiaries	100	100
Total Number of Beneficiaries	32,043,891	32,043,891

[a] Includes all non-institutionalized Medicare beneficiaries except those who enrolled in a Medicare+Choice plan at any point during the calendar year.

[b] Includes out-of-pocket spending by beneficiaries as well as payment by insurers.

Source. National Academy of Social Insurance, 1999; Estimates by Actuarial Research Corporation based on data from the 1995 Medicare Current Beneficiary Survey.

plan.[4] they are, on average, healthier than other beneficiaries suggesting they may have lower than average drug expenditures.[5] As this issue has gained more attention, other independent researchers have begun to analyze this question in greater detail, and I expect we will have better estimates of prescription drug spending by beneficiaries in the coming months.

Prescription Drug Coverage Among Medicare Beneficiaries.

In 1995 about 65 percent of Medicare beneficiaries had some form of prescription coverage (Table 2).[6] Although this estimate suggests more extensive drug coverage than was previously thought, there are two reasons to be concerned about the adequacy of the current system in protecting beneficiaries against the risk of high prescription drug expenses.

First, not all coverage is equal. Supplemental insurance policies vary in the extent to which they help policy-holders with their drug expenses. And second, the protection against high cost of drugs offered by supplemental policies may be eroding over time. This erosion may include both a decline in the percentage of elderly who hold supplemental coverage with drug coverage as well as a decline in the generosity of benefits. These potential shortcomings in coverage become apparent when one considers each form of supplemental insurance separately:

- **Employer-sponsored coverage** (for both retirees and Medicare beneficiaries who continue to work) has traditionally offered among the richest pharmaceutical benefits, with retirees often facing low-deductibles and fixed dollar co-payments for each prescription dispensed. In recent years, the fraction of employers offering supplemental insurance for their retirees and the generosity of these benefits have declined.[7] When offered, such policies

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[4] Davis, M., et al., "Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries" *Health Affairs* (18)1: 231-243, January/February 1999.

[5] U.S. Physician Payment Review Commission, "Risk Selection Remains a Problem in Medicare," PPRC Update No. 21 (Washington, DC: July 1997).

[6] Davis, M., et al., 1999, *op. cit.* These results are higher than previous estimates reflecting methodological improvements in working with the Medicare Current Beneficiary Survey (MCBS) data that brought to light supplemental prescription drug coverage not previously included. See for example, Chulis, G., Eppig, F., and Poisal, J., "Ownership and Average Premiums for Supplementary Insurance Policies," *Health Care Financing Review* (17)1: 255-274, Fall 1995.

[7] In large measure the decline has been caused by accounting standards adopted in 1993, which require firms to record future retiree health benefits as a liability on their balance sheets. McArdle, F., "Presentation on Employer-Provided Retiree Health Benefits," to the Reform Task Force, National Bipartisan Commission on the Future of Medicare, Washington, DC, July 14, 1998. U.S. Congress, General Accounting Office, *Private Health Insurance: Declining Employer Coverage May Affect Access*

Table 2

Outpatient Drug Coverage Among Noninstitutionalized Medicare Beneficiaries by Type of Supplemental Insurance, 1995

	Percent of Beneficiaries with Specified Type of Supplemental Insurance	Percent of Beneficiaries with Each Type of Supplemental Insurance who Have Drug Coverage	Percent of All Beneficiaries with Drug Coverage
Employer Sponsored[a]	33%	86%	28%
Medicaid[b]	12	90	11
Medicare Risk HMO	7	95	7
Individually Purchased (Medigap)	29	29	8
All Other[c]	3	89	3
Switched Coverage During the Year[d]	8	80	6
No Supplemental Insurance	8	0	0
Total	100	N/A	65[e]

Key: N/A-not applicable. HMO-health maintenance organization.

Notes: Data are based on noninstitutionalized, community based population and include those who were enrolled in Medicare at some point during the year. Each person has been assigned to one supplementary insurance category, but they may or may not obtain their drug insurance coverage from that source.

[a]Includes those who only had employer-sponsored supplemental insurance and those who had both employer-sponsored and individually purchased supplemental insurance.

[b]Includes beneficiaries receiving full Medicaid benefits, as well as qualified Medicare beneficiaries (QMBs) and specified low-income Medicare beneficiaries (SLMBs).

[c]Includes other public programs such as Veterans Affairs, Department of Defense, and State Pharmaceutical Assistance Programs for low-income elderly, as well as non-risk HMOs (cost and health care prepayment plans).

[d]Includes beneficiaries who did not spend 100 percent of their Medicare-eligible months in one insurance category.

[e]Column does not add up to total due to rounding error.

Source: National Academy of Social Insurance, 1999. Data from Davis, M., et al., "Prescription Drug Coverage, Utilization, And Spending Among Medicare Beneficiaries " *Health Affairs* 18(1): 231-243, January/February 1999 and the 1995 Medicare Current Beneficiary Survey.

increasingly require retirees to receive their health care through managed care plans, which, while limiting out-of-pocket expenditures, frequently use formularies that limit beneficiaries' access to brand name drugs.

- Many **Medicare HMOs** (now **Medicare+Choice plans**) provide their beneficiaries with some drug coverage. Plans have been able to do this because the federal payments they receive for each Medicare enrollee have been relatively generous in areas in which fee-for service Medicare spending is high. Because federal rules limit the profit margins plans can make on their Medicare business, some plans have chosen to attract beneficiaries by offering extra benefits to Medicare enrollees, including outpatient prescription drugs, for no additional premium. While these plans often require only a small co-payment from beneficiaries for each prescription, most limit their prescription drug payments to $1,000 or less for each beneficiary each year.[8] The Balanced Budget Act of 1997 (P.L. 105-33) will reduce the growth rate in federal payments to Medicare+Choice plans, especially in areas where they have been relatively high. There is anecdotal evidence that plans are reacting by cutting back prescription drug coverage, increasing premiums, or both.[9]

- **Medigap policies**—individually purchased supplementary policies—offer limited or no coverage of prescription drugs. Federal law permits ten standard Medigap policies developed by the National Association of Insurance Commissioners.[10] Only three of these plans (called plans H, I, and J) include prescription drug coverage. The prescription drug benefits in these plans are not particularly generous. Two plans (H and I) pay 50 percent of drug costs up to $1,250 after the beneficiary meets a $250 deductible. Plan J is the same except its maximum benefit is $3,000.

  The costs of these three Medigap plans are high relative to other Medigap plans. To illustrate, Table 3 compares premiums charged in several localities for Medigap plan C (which does not cover prescription drugs) and plan I (which is similar except that it adds limited drug coverage, some home health benefits not included in Medicare, and coverage of all physician charges not

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for 55- to 64-Year-Olds, GAO/HEHS-8-98-133 (Washington, DC: U.S. Government Printing Office, June 1998).

[8] Soumerai, S.B., et al., 1999, *op. cit.* For the details of benefits offered by Medicare+Choice plans throughout the country, see the "Medicare Compare" database at U.S. Health Care Financing Administration website http://www.medicare.gov.

[9] Griffith D. "Drug Costs Up Sharply for Seniors In HMOs" *The Sacramento Bee*, January 24, 1998. Lagnado L, McGinley L, and Tanouye E, "Idea of Having Medicare Pay for Elderly's Drugs is Roiling the Industry, *Wall Street Journal*, February 19, 1999. Hilzengrath D, "In Insurance Curbs, a Prescription For Hardship." *The Washington Post*, May 9, 1999.

[10] Premiums for any given policy vary as well to reflect the risk of the individual except under certain circumstances established by the federal government.

Table 3
Average Annual Premiums of Selected Medigap Policies in Five Cities, 1999

	65 Year Old		75 Year Old	
	Policy C (does not include drug coverage)[a]	**Policy I** (includes outpatient drug coverage)[b]	**Policy C** [a]	**Policy I** [b]
Dallas, TX	$1,046	$2,294	$1,295	$2,974
Denver, CO	974	2,589	1,199	3,221
Los Angeles, CA	1,502	3,362	1,820	4,437
Miami, FL	1,510	3,428	1,890	4,158
Manchester, NH	917	1,945	1,247	2,581

[a] Benefits of Medigap policy "C" are: coverage of all Part A (hospital) coinsurance for stays longer than 60 days, the 20% Part A coinsurance, Parts A and B blood deductible, skilled nursing facility coinsurance, Part A deductible, Part B deductible, medical emergencies while outside the United States.

[b] Benefits of Medigap policy "I" are the same as those of policy "C" except that: (1) policy "I" includes coverage of 50% of outpatient prescription drug expenditures up to $1,250 after meeting a $250 deductible, 100% of any physician fees in excess of Medicare's "reasonable charges," and up to 40 at-home visits during recovery from an acute illness, and (2) policy "I" does not cover the Part B deductible.

Source: "Medicare: New Choices, New Worries," *Consumer Reports* (September 1998): 27-39. Rice, T., Graham, M.L., and Fox, P.D., "The Impact of Policy Standardization on the Medigap Market," *Inquiry* 34 (Summer 1997): 106-116.

paid by Medicare. The added coverage more than doubles the beneficiary's annual premium; the bulk of this difference is attributable to the prescription drug benefit.[11] The difference in premium suggests that the more extensive coverage may attract sicker patients who are heavy users of pharmaceuticals.[12] In addition, those with Medigap policies often pay high prices for their prescriptions. Like Medicare beneficiaries who lack prescription drug coverage, they do not receive the volume discounts that members of employer sponsored and managed care plans often enjoy.

- **Medicaid** coverage is the most comprehensive form of prescription drug coverage for Medicare beneficiaries with incomes low enough to qualify.[13] While many states have received federal waivers allowing them to enroll Medicaid beneficiaries in managed care plans that may not cover all prescription drugs, dually eligible Medicare beneficiaries are exempted from these waivers. In addition, lower income elderly who do not qualify for Medicaid can receive assistance with prescription drug costs in 13 states through state-run programs.[14]

Beneficiaries With No Drug Coverage. What about that 35 percent of Medicare beneficiaries with no insurance beyond Medicare? As shown in Figure 1, poor and near poor beneficiaries are more than twice as likely as non poor beneficiaries to lack any supplemental insurance in addition to Medicare. This indicates that lower income beneficiaries not only have less personal resources to pay for any significant drug

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[11] Rice T., Professor of Health Services, University of California at Los Angeles, personal communications, March 22, 1999. In background analysis conducted for Rice T, M. L. Graham, and P. D. Fox, "The Impact of Policy Standardization on the Medigap Market," *Inquiry* 34 (Summer 1997) 106-116, prescription drug coverage represented 21 percent of the total actuarial value of Plan I or 71 percent of the difference in actuarial values of Plans C and I plus the actuarial value of coverage of the Part B deductible. (Plan I has prescription drugs and two other benefits not found in Plan C, but Plan C offers one benefit not found in Plan I – coverage of the Part B deductible.

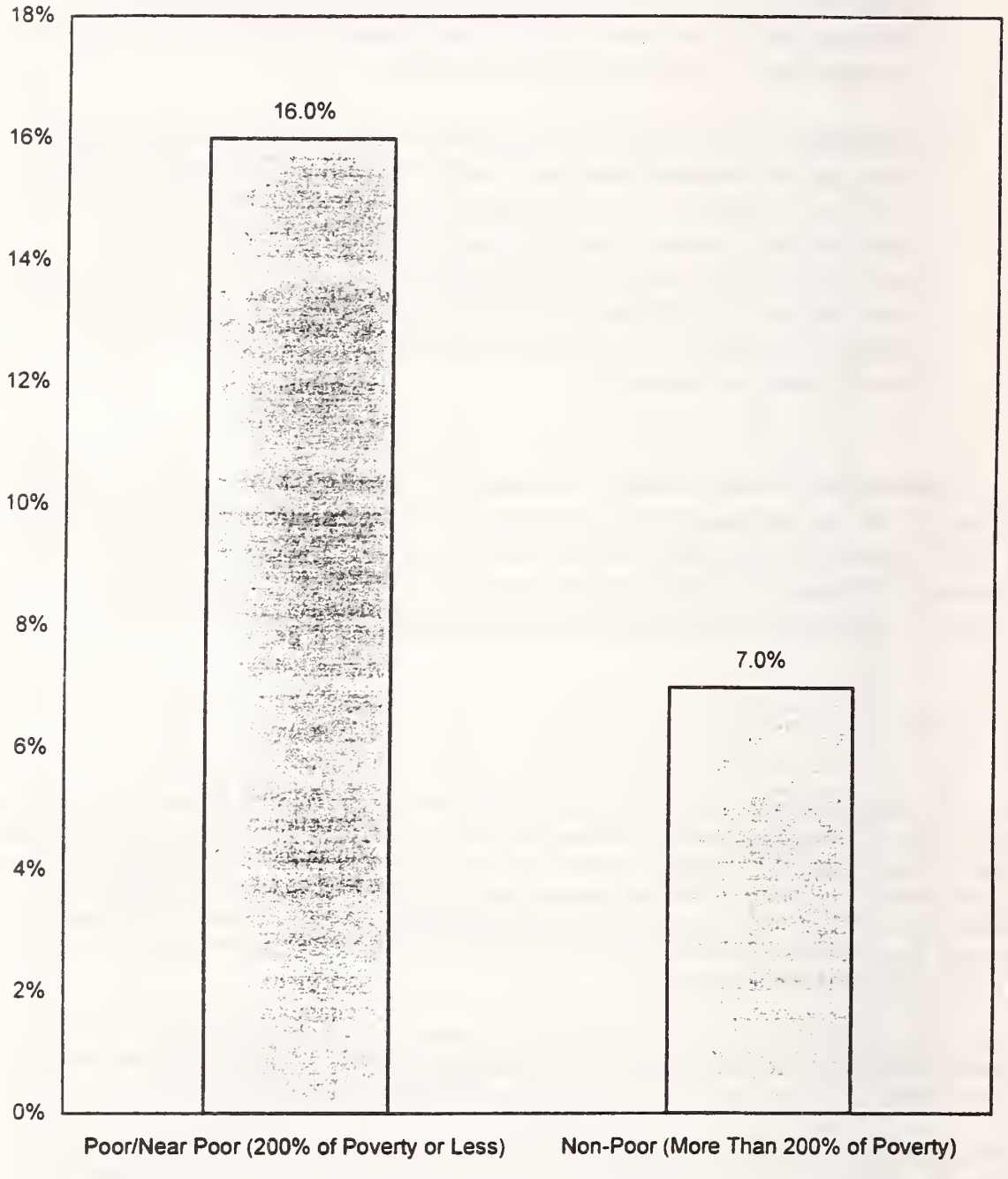
[12] Rice, T., "Problems with the Supplemental Insurance System: Implications for Medicare Reform," commissioned paper for the National Academy of Social Insurance Study Panel on Medicare Financing, November 1998; "Medicare: New Choice, New Worries," *Consumer Reports* (September 1998): 27-38.

[13] This does not include Qualified Medicare Beneficiaries (QMBs) or Specified Limited Medicare Beneficiaries (SLMBs), who receive Medicaid funds to help them pay their Medicare cost-sharing obligations.

[14] States with low income pharmaceutical assistance programs for the elderly in 1999 are: Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, Rhode Island, Vermont according to Kim Moran, Project Coordinator, Communications Department, National Pharmaceutical Council, Incorporated, Reston, Virginia, personal communications, February 23, 1999.

Figure 1

Percentage of Medicare Beneficiaries With No Supplemental Insurance by Income Status, 1995



Source: Henry J. Kaiser Family Foundation, 1999. Data from the Urban Institute analysis of 1995 Medicare Current Beneficiary Survey.

expenses they may incur, but they are also less likely than other beneficiaries to have insurance to help them with those expenses.

In short, this review suggests that substantial numbers of Medicare beneficiaries are at risk of financial hardship due to prescription drug expense and that the number may be on the increase.

Issues in Designing a Medicare Prescription Drug Benefit

If Congress were to consider adding prescription drug coverage to Medicare's benefit package, it would have to grapple with a number of difficult decisions. These include: Who would be covered? What would it cost? How would it be financed? And how would it be administered?

Who would be covered? An outpatient prescription drug benefit can be designed to meet any of several objectives. It could help protect those Medicare beneficiaries with moderate expenses meet their drug expenses, it could protect beneficiaries from catastrophic drug costs, or it could provide assistance to low-income individuals who lack access to prescription drug coverage at an affordable price.

- **Coverage for all beneficiaries**—Under this approach, Medicare would help pay for any beneficiaries' prescriptions once they paid an annual deductible. The lower that policymakers set the deductible, the more people would benefit. A key question for policymakers is whether such coverage would include a maximum benefit similar to those of Medigap polices H, I, and J in order to limit costs. Policymakers would also have to decide how much beneficiaries should pay for each covered prescription. Most employer-sponsored retiree health plans either pay 80 percent of drug costs after the beneficiary has met an overall medical spending deductible or require modest co-payments with each prescription (for example, $5 co-payment for generic drugs,[15] $10-$15 for brand name drugs) but no deductible.[16] Another way to structure the benefit would be to provide beneficiaries with a voucher toward the purchase of private prescription drug insurance policies, which the federal government could choose to standardize as it has done for Medigap insurance.

- **Coverage for beneficiaries with extraordinary drug expenses only**—Under this approach, Medicare would pay a share—for example, 50 percent—of

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[15] Brand name drugs refer to those chemical entities covered by patents and typically manufactured by only one firm. Generic drugs refer to those chemical entities whose patent has expired and are sold by multiple manufacturers, usually at lower prices than brand name drugs.

[16] McArdle, F., *op. cit.*

drug costs above a fairly high deductible—for example, $500. If out-of-pocket spending exceeded a threshold—for example, $2,000—Medicare would pick up all additional costs.[17] This type of benefit helps limit the financial liability of individuals with unusually high pharmaceutical bills, but beneficiaries would need to find other resources to pay for drug expenses up to the deductible as well as the coinsurance amounts.

- **Coverage for low income beneficiaries only**—This approach would help only low income Medicare beneficiaries who lack other prescription drug insurance – in particular, the poor and near-poor who do not qualify for Medicaid.[18] Such a targeted approach would limit the federal government's financial exposure for drugs.

  There are at least two sharply different approaches to providing this type of benefit. One approach would be to provide pharmaceutical coverage to Qualified Medicare Beneficiaries (QMBs), Supplemental Limited Medicare Beneficiaries (SLMBs), and federally Qualified Individuals (QIs). These three groups are low income Medicare beneficiaries who do not qualify for Medicaid, but who receive help in paying their Medicare premiums and cost sharing requirements. Under this approach, policymakers would have to decide how to split the costs of the program between the states and the federal government. Currently, large numbers of individuals who are eligible for QMB and SLMB subsidies do not apply for them.[19]

  An alternative approach would be to provide retrospective tax credits for prescription drug spending. While a tax credit would be relatively easy to administer through tax returns, it would require that beneficiaries pay for their prescriptions up front. In addition, some lower income beneficiaries may not file income tax returns.

What would a benefit cost? Adding a Medicare benefit at a time when the country is wrestling with how to finance current Medicare services makes the cost of

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[17] The Medicare Catastrophic Coverage Act of 1988 (repealed in 1989) offered this type of coverage for pharmaceuticals. Once a beneficiary met a deductible, Medicare would have paid 80 percent of the drug's allowed price. The federal government would have set the deductible each year so that 16.8 percent of beneficiaries would have had prescription drug spending that exceeded the deductible. In the first year of the program (1990), the deductible would have been $550.

[18] In 1997, only 42 percent of poor beneficiaries qualified for Medicaid at any point during the year. Of those with incomes between 100-125 percent of poverty, 20 percent had no supplemental coverage at all; and for those between 126-200 percent of poverty, 16 percent had no supplemental coverage of any type; Gross, D. J., *op. cit.*

[19] The Barents Group, *A Profile of QMB-Eligible and SLMB-Eligible Beneficiaries*, Report to the Health Care Financing Administration. (Washington, DC: April 7, 1999).

drug coverage particularly important. To understand how drug coverage would affect Medicare expenditures, we commissioned Actuarial Research Corporation to estimate the cost of five illustrative drug benefits over the period 1999-2030.[20] One has a maximum benefit of $2,000 per year, while the other four have a "stop loss" (maximum out-of-pocket liability for beneficiaries) that ranges from $1,000 to $3,000 (Table 4). Because we hypothesized that a stop loss feature might be relatively expensive, we chose to estimate the cost of several such benefits to determine whether varying deductibles and coinsurance rates might lessen the fiscal impact of the stop loss feature.

In 1999, the costs of these illustrative benefits would range from $17.5 to $24.0 billion, or 7.2 percent to 10 percent of other projected Medicare expenditures (Table 4). Over the first ten years of these benefits, these benefits would add between 7 and 13 percent to Medicare benefits each year. Our estimates also illustrate the trade-offs between coverage with a maximum benefit (Benefit #1 in Table 4) and coverage with stop loss protection (Benefits #2 through #5) Over time, the costs of a drug benefit with a stop loss guarantee would rise significantly (Figure 2). This occurs because per capita drug costs are projected to rise faster than other Medicare costs, and a stop loss feature essentially protects beneficiaries from such increases. By contrast, coverage that pays no more than a certain amount (Benefit #1) keeps Medicare's expenditures relatively stable by shifting cost increases in pharmaceuticals back to beneficiaries.

How would a benefit be financed? Congress would also have to decide how to finance any pharmaceutical coverage it added to Medicare, including how to split the costs between beneficiaries (probably through a premium) and taxpayers. If pharmaceutical coverage were financed like other Part B services, beneficiaries would pay 25 percent of the cost through their premiums with the remainder coming from general tax revenues. This would reduce the costs to the federal government estimated above by a quarter, but it would add about $9 to $13 to beneficiaries' $45.50 monthly Part B premium in 1999. However, Congress could ask beneficiaries to pay more or less than 25 percent of the cost, and it could decide to finance the taxpayers' portion of the costs through mechanisms other than general revenues.

Because a new pharmaceutical benefit would shift to Medicare some costs now borne by employers for retiree health coverage and by states for beneficiaries dually eligible for Medicare and Medicaid, Congress will also have to decide whether these entities ought to help pay for Medicare drug coverage. Furthermore, if there are subsidies to help lower-income beneficiaries pay any premiums, deductibles, and coinsurance, Congress will have to decide whether states should share in these costs (as they currently do for QMB and SLMB subsidies) or whether they should come from federal funds only (as they currently do for QI subsidies).

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[20] More detail about these cost estimates, including the assumptions made to produce them, may be found in Gluck, M.E., *op. cit.*

Table 4

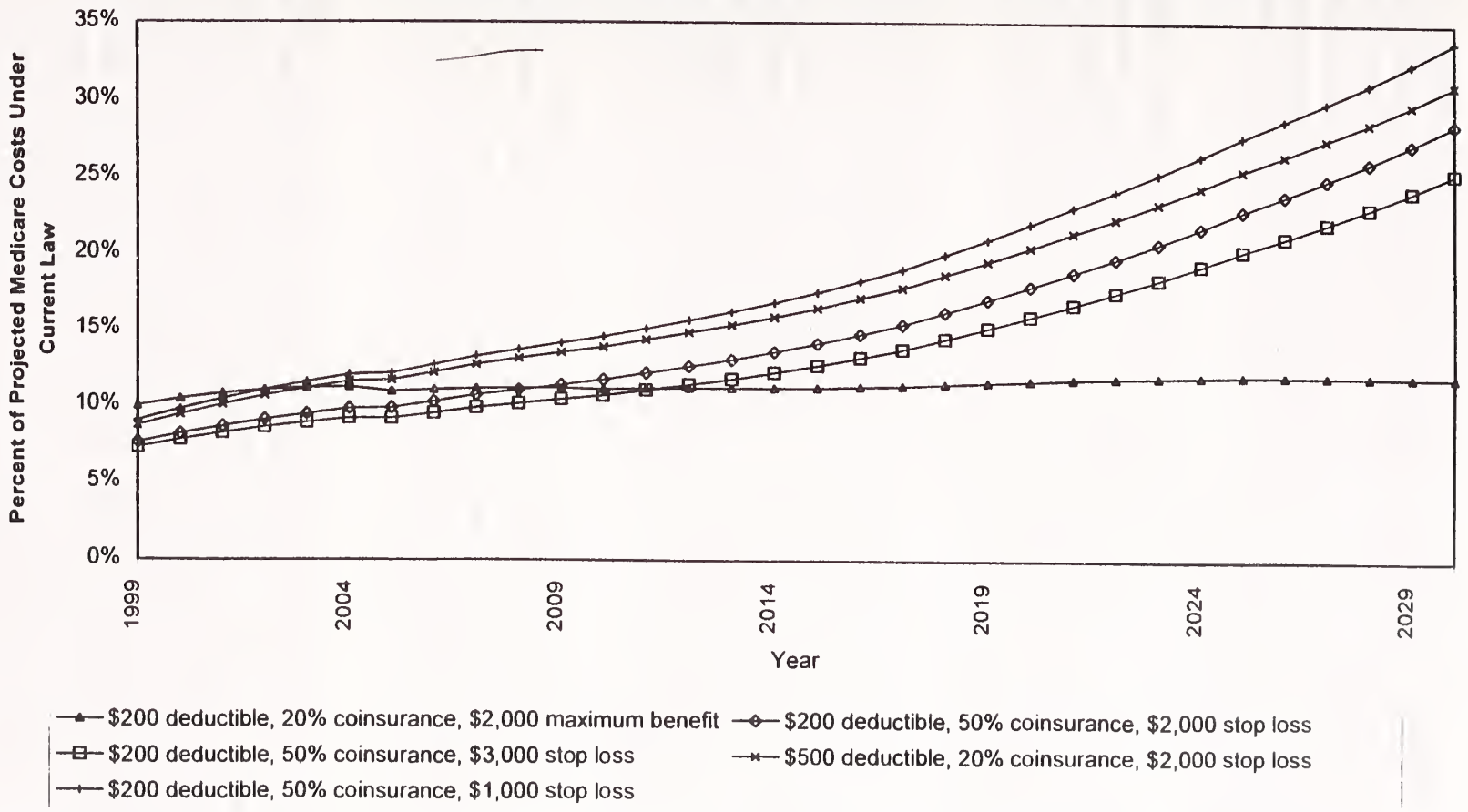
Estimated Cost of Five Illustrative Medicare Drug Benefits, 1999

Benefit	Cost Per Beneficiary	Total Cost ($ Billions)	Percent Increase in Medicare Costs
#1: $200 deductible, 20% coinsurance, $2,000 maximum benefit	$609	24.0	10.0%
#2: $200 deductible, 50% coinsurance, $2,000 stop loss	$463	18.3	7.6%
#3: $200 deductible, 50% coinsurance, $3,000 stop loss	$443	17.5	7.2%
#4: $500 deductible, 20% coinsurance, $2,000 stop loss	$530	20.9	8.7%
#5: $200 deductible, 50% coinsurance, $1,000 stop loss	$552	21.7	9.0%

Source. National Academy of Social Insurance, 1999; Estimates by Actuarial Research Corporation, based on data from 1995 Medicare Current Beneficiary Survey.

Figure 2

Estimated Cost of Five Illustrative Medicare Drug Benefits as a Percentage of Projected Medicare Costs Under Current Law, 1999-2030
(Assumes Nominal Annual Growth Rate in Per Capita Prescription Drug Spending of 8.3% After 2008)



Source: National Academy of Social Insurance, 1999, Estimates by Actuarial Research Corporation, based on data from 1995 Medicare Current Beneficiary Survey

How is the Benefit to be Administered? No matter what form a prescription drug benefit took, it would raise a number of administrative questions. Except for a tax credit, policymakers would have to decide who would manage the benefit for those enrolled in the traditional, fee-for-service part of the program. (Presumably, health plans would administer the benefit for those enrolled in Medicare+Choice, although the government would still have a role in setting and enforcing standards for drug coverage offered by the private health plans.)

If HCFA or its contractors were to process individual claims as they do for other Medicare services, the agency would need to oversee establishing relationships with providers (pharmacies) and standardizing the claims filing and payment processes. Overseeing claims processing of other covered services has been one of HCFA's core functions, and the agency has had some oversight role and understanding of how state agencies have administered Medicaid's drug benefit.

If HCFA were to administer the benefit, policymakers would have to specify a method for determining reimbursable prices for pharmaceuticals. Medicare could adopt the pricing formula already used by Medicaid under which the federal government has mandated that it receive a rebate from pharmaceutical manufacturers.[21] An alternative would be for the federal government to negotiate prices directly with manufacturers, perhaps with the use of formularies, as described in the next paragraph. No matter what option policymakers choose, the pricing of drugs reimbursed by Medicare would be controversial given the dominant role the program would play in the market for pharmaceuticals.

Policymakers would have to make a decision about whether to cover all drugs under all prescribed circumstances. When there is more than one drug on the market that treats a given condition in a particular way, the decision of an insurer to reimburse for only a limited number of them can foster price competition among manufacturers that

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[21] For "non-innovator, multiple source drugs," (i.e. those not covered by patents that prevent generic manufacturing), the rebate is equal to 11 percent of the average manufacturer price (AMP) per unit of drug sold. For innovator drugs (i.e. those covered by patents that prevent generic manufacturing, the rebate is equal to (1) 15.1 percent of AMP or (2) the difference between AMP and the best price plus an additional rebate based on increases in the drug's cost that exceed overall inflation in the economy (based on the CPI-U) since the drug entered the market. AWP is the drug's list price before discounts. AMP is the price of the drug net of all discounts provided to private purchasers. Best price is the lowest price charged to any purchaser in the United States including wholesalers, retailers, nonprofit organizations, and governmental agencies. These definitions are provided in the rebate agreement between the Secretary of Health and Human Services and pharmaceutical manufacturers which may be found through the worldwide web at http://www.hcfa.gov/medicaid.drug8.htm. For a more detailed description of the Medicaid rebate program and its possible unintended impact of reducing discounts given to private purchasers of drugs, see U.S. Congress, Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (Washington, DC: U.S. Government Printing Office, January 1996) and U.S. Congress, General Accounting Office, *Medicaid: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain*, GAO/HEHS-94-194FS (Washington, DC: U.S. Government Printing Office, 1997).

produces costs savings. Lists of reimbursable drugs are referred to as formularies and have been increasingly used by private health insurers. The more restrictive the formulary, the greater the bargaining power and cost savings for the insurer.[22] Although restricting access to FDA-approved therapies might be a controversial undertaking for Medicare,[23] the desire to balance the needs of beneficiaries, manufacturers, and the public fisc may make this an option that policymakers will need to consider. In addition, at least one national group that advocates on behalf of Medicare beneficiaries, the American Association of Retired Persons, does not oppose the use of formularies by health plans and other providers as long as they maintain certain protections for patients.[24]

An alternative to HCFA administering a prescription drug benefit itself would be to adopt a "carve out" model like those used by private health insurers. Firms that administer pharmaceutical insurance programs under contract to health plans are referred to as pharmaceutical benefit management companies or PBMs. HCFA could contract with PBMs on a capitated basis (i.e., for a set amount per Medicare enrollee) or through partial capitation in which the PBMs receive supplemental payments for patients with extraordinarily high pharmaceutical utilization.[25]

Because PBMs save money by negotiating discounts and rebates from drug manufacturers, wholesalers, and pharmacies in exchange for being able to steer patients to particular products, largely through formularies,[26] saving money under this option would depend on PBMs ability to adopt formularies for Medicare beneficiaries as mentioned above. More generally, to what extent would the government regulate the PBMs and the benefits they provide? In considering options for a privately administered benefit, policymakers would have to weigh the simplicity of limited government

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[22] U.S. Congress, Congressional Budget Office, *op. cit.*; U.S. Congress, Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (Washington, DC: U.S. Government Printing Office, July 1998).

[23] Some state Medicaid programs used formularies until the Omnibus Budget Reconciliation Act (OBRA) of 1990, the same law that established the rebate program described in note #21, prohibited them.

[24] In particular, AARP states that health plans who use formularies should: "ensure participation of plan physicians in the development of the formulary; disclose the nature of formulary restrictions and utilization management policies; inform the plans members about whether the drug benefit is being managed by a PBM as well as the PBM's parent company; and make allowance for formulary exceptions when medical necessity dictates that a nonformulary alternative is needed, and ensure that plan members are aware of how such alternatives can be obtained." Gross, D, Senior Policy Advisory, AARP Public Policy Institute, Washington, DC, personal communications, March 18, 1999.

[2525] Reimbursing PBMs on a purely fee-for-service basis (i.e. a reimbursement for each pharmaceutical used) would be equivalent to the PBMs acting as a claims processor without necessarily having incentives to be prudent purchasers or otherwise cost conscious. The federal government would retain all of the responsibilities for deciding about pricing and formularies outlined above.

[26] U.S. Congress, Congressional Budget Office, July 1998, *op. cit.*

involvement against the need to provide sufficient oversight to protect beneficiaries and taxpayers.

The Choices We Face

In essence, we face the same kind of question we faced as a Nation in 1965 when we created Medicare. The program was initially designed to provide retirees and people who can no longer work due to disability with the same health insurance coverage as that generally available to the working population through employer-based insurance. Medicare no longer provides equivalent coverage; outpatient prescription drugs are an essential component of modern health care and failure to cover their costs is a major gap in the protection promised by Medicare.

The question is whether we want to use the mechanism of social insurance to spread the risk of prohibitive prescription drug expenses for beneficiaries. Prescription drug costs could be integrated into the benefits package to provide equal coverage to all beneficiaries, regardless of health status, in the same way that other insurance costs are spread across the participant population in a national entitlement program. Alternatively, we could continue to explore new ways to integrate public, employer-based and individual responsibility for covering these costs. In any case, the costs for prescription drugs for seniors and people with disabilities will continue to grow.

Although the financial hardship posed by prescription drug costs for most beneficiaries today are not as great as the burden that health care placed on seniors in 1965, our analysis suggests that it is significant for many beneficiaries. Access to insurance coverage for prescription drugs for individuals with modest incomes is increasingly difficult. The data support the observations found in many recent newspaper articles that a substantial minority of seniors are forced to choose between pharmaceuticals that protect their health and other necessities. Further, the dramatic growth in biomedical research promises ever increasing numbers of new drugs that prolong and improve life, but often at significant expense. As in 1965, there is no convincing evidence that the private market will be able to address adequately the insurance needs of people with low-to-moderate incomes who are at risk of incurring very high costs for outpatient prescription drugs.

Unlike 1965, however, a potential expansion in Medicare benefits comes at a time when we are trying to decide how we will finance the services already covered by Medicare. Furthermore, we know today that new benefits can be complicated to set up and administer and that they can have unintended consequences. It will not be easy for Congress and the American people decide what role Medicare will play in helping beneficiaries pay for the drug therapies that will make up an ever-increasing portion of our health care arsenal. The philosophical choices will be tough, and the technical questions will be complicated.

ERRATA

Page 5, last paragraph of text, second sentence should read: "What about that 35 percent of Medicare beneficiaries with no drug coverage?"

Statement

PhRMA

Alan F. Holmer
President
Pharmaceutical Research and Manufacturers of America

before the

Committee on Finance
United States Senate

June 23, 1999

Introduction

Mr. Chairman, Senator Moynihan, other members of the Committee, I'm pleased to be with you this morning to discuss the subject of prescription drug coverage for seniors and the disabled. I'm here on behalf of America's pharmaceutical industry, employers of the women and men who spend every day searching for cures and treatments to allow all Americans to stay healthy and lead longer, better lives.

Attachment 1 to this Statement summarizes a few of the key data points regarding our industry and its research.

Our overall view is straightforward: Anytime any patient is unable to obtain access to our medicines, our member companies are concerned. We want to be part of a solution that helps seniors and the disabled obtain the medicines they need, without discouraging the discovery and development of new medicines to help and heal more patients.

The research-based pharmaceutical industry supports expanding prescription drug coverage for seniors and the disabled -- but it needs to be done the right way, through a modernized Medicare program that gives beneficiaries good choices between different kinds of competing private-sector health plans.

Overall Perspective

Mr. Chairman, I'd like to introduce this subject by reading a passage from the Russian writer Leo Tolstoy. Don't worry, it's not War and Peace. It's a short selection from A Child's Garden of Morals.

> The grandfather had become very old. His legs wouldn't go. His eyes didn't see. His ears didn't hear. He had no teeth....
>
> His son and daughter-in-law stopped setting a place for him at the table and gave him supper in back of the stove. Since age had made him clumsy, they didn't serve his food on a plate. Instead, they put his dinner in a dishpan. The old man sighed and said nothing.
>
> One day the couple watched their small son playing on the floor with some pieces of wood.
>
> "What are you doing?" they asked.
>
> "Dear Father" he said. "I am making a dishpan so that when you and Mother grow old, you may eat from this dishpan."
>
> The husband and wife looked at each other and wept. From then on, they seated the old man at the table and waited on him.

The temptation to sweep aside the uncomfortable sight of the old and infirm has been, throughout time, in tension with the respect and debt owed to them by rising generations. In our day, because of new medicines, we are on the brink of turning old age from a ledge of life to be feared into perhaps the most pleasant, rewarding plateau of them all. This possibility is at the center of the coming national debate over Medicare.

Our challenge is this: How can we ensure that affordable medicines are available to our senior citizens, without discouraging the discovery and development of new cures and treatments? We need to remember a fundamental truth: seniors want access to our medicines because they were invented.

Thanks to modern medicines, today's seniors live longer, healthier, better lives. At the turn of the last century, the average age at death was 47. Few had the luxury of worrying about old age. Today, thanks in part to medicines, average life expectancy is 76. Every five years since 1965, medicines have helped add one year to average life expectancy. And many people are well above average. There are 1.4 million Americans in their nineties and an additional 64,000 who are 100 or older. And I regularly say a prayer that my own parents – tennis-playing octogenarians – will one day be among them.

In fact, those of us baby boomers represent the first generation of Americans who, on average, have more parents than children.

If Tolstoy's grandfather figure were living here and now, his story would be very different, largely because of this past decade's new medicines that help and heal. Tolstoy's grandfather wouldn't be crippled by arthritis – he'd be taking one of the nine new medicines pharmaceutical companies have developed to treat this condition. He probably wouldn't be blind, because he'd have the choice of five medicines available for glaucoma. Thanks to the 45 medicines for heart disease approved over the past decade and the 33 for cancer and dozens more for other diseases of aging, he might well be just as fit and active as my Mom and Dad.

Pharmaceutical research is even making headway against one of the cruelest diseases of aging – Alzheimer's. At a stage in life when people yearn to enjoy their memories, Alzheimer's steals them, breaking the hearts of patients and their families. I know that this is an anxiety that some members of this committee have experienced in their families firsthand.

I don't know anyone in my or my parent's generation who doesn't dread this terrible disease, who doesn't wonder: "Will there be a cure before Alzheimer's strikes me?" The best hope for a "Yes" answer to that question is the pharmaceutical industry.

Pharmaceutical companies have 19 medicines in testing for Alzheimer's, and they're using cutting-edge research to get at – and stop – the root causes of this disease.

This research is important, not only to our physical and mental health, but also to our country's economic health. The disease costs our society some $100 billion a year – and this cost will go up as the baby-boom generation ages. If we can control this terrible disease, we can control its terrible cost. In fact, medicines are beginning to do just that. In a recent study, patients treated with a new medicine for Alzheimer's were only half as likely to require costly nursing home care as patients who didn't get the medicine.

It's important to remember that most seniors do have access to breakthrough medicines. About two-thirds of seniors have prescription drug coverage from one source or another. Through employer-provided retiree health plans. Or state assistance programs. Or Medigap insurance or Medicare+Choice plans.

Still more seniors obtain needed medicines through the generous patient assistance programs run by pharmaceutical companies – programs that helped more than 1.5 million American patients last year.

People like the South Carolina woman who wrote to thank one of our companies for the medicine that's easing her colitis. "It's because of your help that I can take my medicine and start to feel better," she said. "It's really nice to know that your company cares enough to help people in need."

And, because we care, we want to bring the benefits of innovative research to all seniors.

But we want to do it right. We want to spread the light cast by the fire of innovation, without snuffing it out. We want seniors and the disabled – and all patients – to have full access to the best medicines we can devise. We want seniors and the disabled to sit at the table for the feast of innovation – not to be shunted to the dishpan at the back of the stove.

Suggested Principles/Questions for Addressing This Issue

The challenge the Committee faces in addressing this issue is best illustrated by a sign over the counter of a local print shop; it warns customers: "Price, Speed, Quality – Pick Two."

As you approach the issue of prescription drug coverage for seniors, we hope that you will ask the following hard questions with respect to each proposal that you consider:

- What will be the long-term impact of this proposal: on elderly and disabled patients, on the Medicare program, and on the pharmaceutical industry that all patients are counting on to discover and develop medicines in the first place?

- Long-term, is this proposal the best way to improve quality health care for patients, integrate care, and manage costs?

- Will this proposal strengthen and modernize the Medicare program, or will it just tack on an expensive drug benefit to an outmoded program headed for insolvency?

- Does the proposal encourage integrated decisions about treatment of patients and budgeting of those treatments, as opposed to making treatment and budget decisions about drugs in isolation?

- Does the proposal provide extra financial help to those with low incomes? Does it provide special attention to groups with special needs, including the disabled?

- Will the proposal displace existing sources of private coverage or financing, increasing the costs of the program and/or reducing its effectiveness?

- For cost containment, does the proposal rely on vigorous competition among different kinds of private health plans, or does it rely on government-imposed price controls and regulations?

- Who will run the program -- the Health Care Financing Administration, with its 132,000 pages of regulations and red tape that are strangling the health care system? (As Senator Moynihan noted last week, HCFA's Medicare regulations are three times as lengthy as those for the entire Internal Revenue Service.)

    - Despite the best of intentions, won't a HCFA-run program inevitably lead to government-imposed price controls?

- Does the proposal address the multiple problems of waste, fraud and abuse in Medicare?

- Will this proposal expand choices in medicines for seniors, or will it ultimately lead to restrictions on access to medicines imposed by the government or its agents?

- Will this proposal be adequately financed? Will the overall proposal improve the fiscal solvency of Medicare?

- What impact will this proposal have on the ability of the American pharmaceutical industry to continue its record-breaking path of innovation?

Attachment 2 states PhRMA's Principles for strengthening and modernizing Medicare and improving prescription drug coverage for beneficiaries.

Application of Principles to Pending Proposals

When we apply our principles to proposals currently before the Committee, we reach the following conclusions:

Medicare Commission

A majority of members of the National Bipartisan Medicare Commission – including three members of this Committee – recommend that we strengthen and modernize the Medicare program. How? By ensuring that seniors and the

disabled can choose the health plan that best serves their individual health care needs, from an array of various kinds of competing private-sector plans.

We are generally encouraged by the premium-support proposal supported by Senators Breaux, Kerrey and Gramm because they would promote key objectives for Medicare reform: high-quality, integrated health care for seniors and the disabled, and cost-containment based on market competition, not government price controls and regulations, to promote a fiscally strong program for seniors today and tomorrow.

Of course, the details are important, especially in such a complex, technical area, and we haven't seen Senator Breaux's bill yet. We support private-sector health care choices and oppose enlargement of the existing HCFA program, which is based on government price controls and stifling regulations. Therefore, we do not favor the idea of improving prescription drug coverage in the existing HCFA-run fee-for-service program, which would discourage enrollment in private-sector fee-for-service and other types of health plans and, over time, would surely lead to government price controls. We want to improve beneficiaries' prescription drug coverage through the private sector, in the context of a modernized Medicare program – and we think that generally the Bipartisan Commission's majority recommendations offer a healthy prescription for achieving these results.

S. 731, the Prescription Drug Fairness for Seniors Act of 1999

This bill, pursued by Senator Kennedy, would require manufacturers to sell drugs to pharmacies at the lowest price that pharmaceutical manufacturers are already compelled by law to give to specified federal departments. PhRMA's view of this legislation is summarized at Attachment 3.

This bill is a shining example of quick-fix thinking that is penny-wise but pound-foolish. It would put over 40 percent of the U.S. pharmaceutical market under the iron grip of government price controls. For diseases like Alzheimer's that afflict primarily seniors, virtually 100 percent of medicines would be under government price controls.

If anybody wants more proof that government price controls on pharmaceuticals don't work, they need look no further than an April 1999 study by the Boston Consulting Group. The study looks at what happens – to drug spending, to health care spending, and to patients -- when governments intervene in the pharmaceutical marketplace. Here are a few highlights:

- From 1990 to 1997, the U.S., with its relatively free market for pharmaceuticals, saw annual growth in pharmaceutical spending that was lower than that of countries with price controls. (Attachment 4A)

- Even when government price controls "work" in the short term to lower pharmaceutical spending, they often result in higher spending on other health care services. That's what happened when Germany squeezed the balloon by introducing so-called physicians' drug budgets in 1993. The balloon popped out in other places, raising hospital admissions by 10 percent and specialist referrals by another 10 percent. (Attachment 4B)

- Price controls hurt patients by delaying access to innovative medicines after they have been approved for sale in a particular market. Patients in Greece, Belgium, France, and Switzerland – countries with heavy government intervention in the pharmaceutical marketplace – have to wait as much as 5 to 6 times longer for new medicines than patients in the U.S. (Attachment 4C)

- Price controls delay generic competition. For example, look at what happened when the first H2 antagonist drug for ulcers went off patent in the U.S., compared to the same event in France, a country with rigid price controls. In the U.S., in the first year following patent expiration, the price fell 25 percent. By contrast, in France, the price fell only four percent. (Attachment 4D)

But no matter how much evidence we amass against government-imposed price controls, governments gravitate toward them. As a result, government programs tend to be high on bureaucracy, low on quality and take a myopic view of innovation.

S. 841, the Access to Prescription Medications in Medicare Act of 1999

This bill would require the Secretary of Health and Human Services to contract with various entities to provide a government-administered managed prescription drug benefit to Medicare beneficiaries.

As drafted, S. 841 includes price controls on pharmaceuticals, as described in Attachment 5. We note, however, that Senator Kennedy's staff has indicated a willingness to address these price control issues.

More fundamentally, however, the approach advocated by Senator Kennedy, Senator Rockefeller and others in S. 841 focuses narrowly on Medicare prescription drug coverage and does not seek to modernize or strengthen the Medicare program overall. We think it is short-sighted to focus on medicines in isolation. To promote both high-quality, patient-centered health care and cost-effectiveness (and thereby containment of Medicare costs), we need to prescribe public policy solutions that integrate prescription medicines with other health care options, with respect to both patient treatment and

budgeting. A narrow focus on medicines, in isolation, would lead to suboptimal results for the American people.

Senator Kennedy has described S. 841 as a market-based approach to improving Medicare beneficiaries' prescription drug coverage. We respectfuily but strongly disagree.

The proposed legislation is not a private-sector approach – it is simply a new, big government program, through hired hands. HCFA would be given sweeping new authority to regulate pharmacies, pharmacy benefit management companies, insurers, and pharmaceutical manufacturers. As the experience with Medicare+Choice program has shown, HCFA is stretched beyond its capacity. Many believe it lacks vital expertise, and has not been able to perform its functions effectively.

Inevitably, this "command and control," big government approach would stifle innovation and lead to restrictions on access to medicines. What we need is more choice for seniors, more access, more coverage. What we don't need is more restrictions, more bureaucracy, more government red tape.

Attachment 6 summarizes PhRMA's position on S. 841.

S. 1204, the Healthy Seniors Promotion Act of 1999

We've also reviewed with care Senator Graham's bill, S. 1204, which focuses on preventive health care services and would provide prescription drug coverage for hypertension, glaucoma, smoking cessation and hormone replacement therapies. While we appreciate the bill's good intentions and the value of preventive medicine in general, we would prefer facing up now to the larger, harder, but more important task: strengthening and modernizing the Medicare program overall, and improving prescription coverage for all diseases and health conditions.

A Final Personal Note

Mr. Chairman, I've shared with you my views today as President of PhRMA. Following Father's Day this past Sunday, I'd also like to share with you my views as a Dad.

As some members of the Committee know, I have two children, both of whom have cystic fibrosis. My son, Scott, is a sophomore at Georgetown University, and his sister, Joy, is a junior at Langley High in McLean. They're both doing wonderfully, thanks in large part to the medical breakthroughs of the pharmaceutical industry.

When my son was diagnosed over 19 years ago, the average life expectancy for a child with cystic fibrosis was 18 years. I called the Cystic Fibrosis Foundation yesterday, and they told me that the average life expectancy for a child with cystic fibrosis is now 31 years. I told them that there are now at least 14 medicines in development to treat or cure this disease. We also know that the average time for getting a new medicine from the laboratory bench to the medicine chest is somewhere between 12 to 15 years.

You can do the math as well as I can. My son's 19 and my daughter's 17. Twelve to 15 years to get a medicine to market. Average life expectancy 31.

There is no doubt in my mind that the cure for cystic fibrosis will be found within my lifetime. What I'm less sure about is whether that cure will be found within the lifetimes of my children.

Why do I talk about my teen-agers in a discussion about drugs for seniors and the disabled? Because this debate is really about quality health care for all Americans, which depends upon private industry's continued drug discovery and development.

So, Mr. Chairman, and all Senators, if I leave you today with only one message, let it be this: At some point in the not-too-distant future, a Congress will pass, and a President will sign, legislation to expand drug coverage for Medicare beneficiaries. It's going to happen.

Some say that this issue is life or death for the pharmaceutical industry, America's premier high-technology industry. After the debate is over, and the dust settles, we'll still have a pharmaceutical industry, but depending on what you do, the industry could be profoundly different, and the results for patients could be demonstrably less.

As the debate unfolds, I hope you'll remember the millions of Americans, like my children, waiting impatiently for new cures and treatments. We can provide quality health care for seniors and the disabled, including better prescription drug coverage, but we need to do it the right way. If we do it the wrong way, the industry and the patients we serve will undoubtedly suffer the consequences.

Attachments

The Research-Based Pharmaceutical Industry: Facts at a Glance

A Strong Commitment to Research and Development

- This year, research-based pharmaceutical companies will invest $24.0 billion in research and development on innovative new medicines. This represents an increase of 14.1 percent over research spending in 1998, and since 1990, research-based companies have more than doubled their R&D expenditures.

- Domestic R&D is expected to increase by nearly 17 percent in 1999. By comparison, R&D conducted abroad by U.S. based companies will grow only 2.1 percent – a clear sign that the American system nurtures innovation and discovery.

- Over the past two decades, the percentage of sales allocated to pharmaceutical R&D has increased from 11.9 percent in 1980 to approximately 20.8 percent in 1999, higher than virtually any other industry. The average for all U.S. industries is less than four percent.

- Approximately 36 percent of pharmaceutical R&D conducted by companies worldwide is performed in the United States, followed by Japan with 19 percent.

- Of 152 major global drugs developed between 1975 and 1994, 45 percent are of U.S. origin. The next highest percentage was the U.K., with 14 percent.

Drug Discovery and Development is High-Risk

- During the 1990s, the average time to develop a new drug increased to 15 years. This is almost twice the development time in the 1960s.

- On average, of every 15,000 compounds initially screened as potential new drugs, only three will make it to market and only one will turn a profit.

  - A 1994 study by health economists at Duke University found that only three of every ten new drugs earned more than their average R&D costs. In other words, companies must rely on a few successful products to finance continuing R&D.

- The Boston Consulting Group estimates that the pre-tax cost of developing a drug introduced in 1990 was $500 million, including the cost of research failures and interest over the period of the investment.

Attachment 1

Medicines in Development

- The industry currently has more than 1,000 new medicines in development to treat hundreds of serious diseases.

- Among these drugs in development are promising new treatments for cancer, heart disease, Alzheimer's, AIDS, diabetes, multiple sclerosis, Parkinson's, stroke, arthritis, and depression.

The Value of Medicines

- The estimated life-expectancy of an American born in 1920 was 54 years. Forty-five years later, in 1965, life expectancy had increased to 70 years. By 1995, it had increased another six years. In fact, we are adding, on average, another year to the average life-span about every five years. These increases are due in part to advances in medicine and our improved ability to prevent, cure, and treat disease.

- In a year-long disease-management program for about 1,100 patients with congestive heart failure run by Humana Hospitals, pharmacy costs increased by 60 percent, while hospital costs declined 78 percent. The net savings were $9.3 million.

- A National Institutes of Health (NIH) study showed that while it initially costs more to treat stroke patients with a clot-busting drug, the expense is more than offset by reduced rehabilitation and nursing home costs. Treatment with the clot-buster costs an additional $1,700 per patient, but reduced rehabilitation and nursing-home costs result in net savings of more than $4,000 per patient.

- In a 1993 study, cancer patients whose immune systems were weakened by high-dose chemotherapy were helped by a new pharmaceutical known as colony-stimulating factor. The treatment saves $30,000 per patient in hospitalization costs for bone-marrow transplants.

- Estrogen-replacement therapy can help aging women avoid osteoporosis and crippling hip fractures, a major cause of nursing home admissions. Estrogen-replacement therapy costs approximately $3,000 for 15 years of treatment, while a hip fracture costs an estimated $41,000.

- The combination of two drugs, at a cost of about $140, can eradicate the bacterial cause of most ulcers. Ulcer surgery costs upward of $28,000.

June 23, 1999

February 18, 1999

STATEMENT OF THE
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
ON STRENGTHENING AND MODERNIZING MEDICARE

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to the discovery and development of new medicines that allow patients to lead longer, healthier, and more productive lives.

A New Vision for Medicare

PhRMA supports expanding prescription drug coverage for Medicare beneficiaries as part of a program that is modernized to allow beneficiaries to choose among qualified, private-sector health plans that rely on market competition, not government regulation or price controls, to improve quality, integrate care, and manage costs. Because moving to such a system may take time, PhRMA supports, as part of legislation to create such a system, interim step to increase beneficiary access to private-sector prescription drug coverage by building on, and not displacing, existing sources of private coverage or financing.

Providing beneficiaries with meaningful choices among market-based health plans encourages innovation and yields the highest quality care for patients. Under this approach, the federal government would make a financial contribution to help Medicare beneficiaries purchase a health plan; beneficiaries would be free to select from a range of private-sector options the plan that best satisfies their individual needs.

Low-income beneficiaries should receive additional assistance to ensure their access to affordable health care. The health care of costly beneficiary subpopulations – including the disabled – is of particular concern and should receive special attention.

To ensure continued high-quality care for Medicare beneficiaries, any improvements must be adequately financed, without resort to government-imposed price controls. Price controls distort the market and reduce incentives to discover and develop breakthrough medicines. Because they would have serious consequences for the health of today's and tomorrow's seniors, PhRMA would vigorously oppose any effort to impose direct or indirect price controls on prescription medicines.

Attachment 2

The Need for a Modern Medicare Program

In the nearly 35 years since Medicare was established, we have seen a revolution in medicine – in what we know about disease and how we apply this knowledge to help patients. In the 1960s when Medicare was created, our ability to diagnose and treat disease was limited. Since that time, because of profound advances in science and medicine, we have found the key to understanding many diseases and are on the verge of even greater discoveries. Modern prescription medicines are among the most important medical advances this age of discovery has produced.

While medical care has made great advances, Medicare has not. Today's Medicare structure does not efficiently meet the health care needs of today's – and tomorrow's – seniors and disabled. To meet the challenge of providing high-quality, cost-effective health care today and for years to come, Medicare should make available to its beneficiaries the health care delivery innovations developed by the private sector.

Medicare now provides limited coverage for prescription medicines. Medicines save lives, cure and prevent disease, relieve pain, and improve the quality of life for patients. They also help people avoid disability, surgery, hospitalization, and nursing home care, and often decrease the total cost of treating an illness. As changes are considered to the Medicare program, one goal should be to enhance beneficiary access to innovative medicines by providing them with choices among competing private sector health plans – while promoting the research-based pharmaceutical industry's ability to discover and develop innovative new medicines for patients.

Principles for Medicare Reform

PhRMA supports Medicare reforms that would ensure Medicare beneficiaries have access to high-quality, cost-effective health care. Under these guiding principles of access, quality, and affordability, Medicare reform should accomplish the following:

Access

- Facilitate the delivery of care through competitive, market-based health plans and plan types,
- Support ample choices among market-based health plans for Medicare beneficiaries, including those current, successful approaches already in place,

- Ensure access to the full range of medicines approved by the Food and Drug Administration,

- Reimburse health plans and providers adequately, and

- Provide beneficiaries information necessary to make informed health care choices.

Quality

- Promote integrated health care delivery and financing,

- Facilitate high-quality patient care by encouraging innovation and evidence-based quality improvement, and

- Promote the rapid diffusion of new technologies to those who would benefit from them.

Affordability

- Rely on competition and the private sector to control costs, instead of government-mandated prices, discounts, rebates and other forms of government price controls,

- Secure long-term fiscal soundness of the Medicare program,

- Streamline Medicare program administration to eliminate unnecessary burdens on providers, suppliers, and beneficiaries.

In addition, PhRMA believes that any expansion of prescription drug coverage for Medicare beneficiaries should be designed to:

- Improve coverage of prescription drugs through the private sector rather than the traditional Medicare fee-for-service program, and

- Improve patient care by promoting strong incentives for the discovery and development of innovative new prescription medicines.

A Medicare program that meets these criteria will more likely promote the optimal use of innovative prescription medicines, resulting in better health for Medicare beneficiaries and, for many diseases and conditions, lower costs to the Medicare program.

DRUG FAIRNESS FOR SENIORS LEGISLATION

What It Is

- S. 731 (H.R. 664), the Prescription Drug Fairness for Seniors Act, was introduced on March 25, 1999 by Senator Edward Kennedy.

What It Does

- This bill would allow pharmacies to purchase drugs at the lowest price that pharmaceutical manufacturers give to any federal department or agency, including Medicaid, the veterans health care system, military treatment facilities, and the Indian Health Service.

Analysis

- This bill would greatly expand government price controls in the pharmaceutical market. If it were enacted, the share of the market subject to government price controls would increase from 15 percent to more than 40 percent.

- This legislation promises lower prices to pharmacies, not seniors. Government-controlled prices are extended to pharmacies, but pharmacies are not required to share the savings with Medicare beneficiaries.

- This bill would not expand drug coverage of Medicare beneficiaries. Any senior who has difficulty paying for medicines could still have difficulty if the bill were enacted.

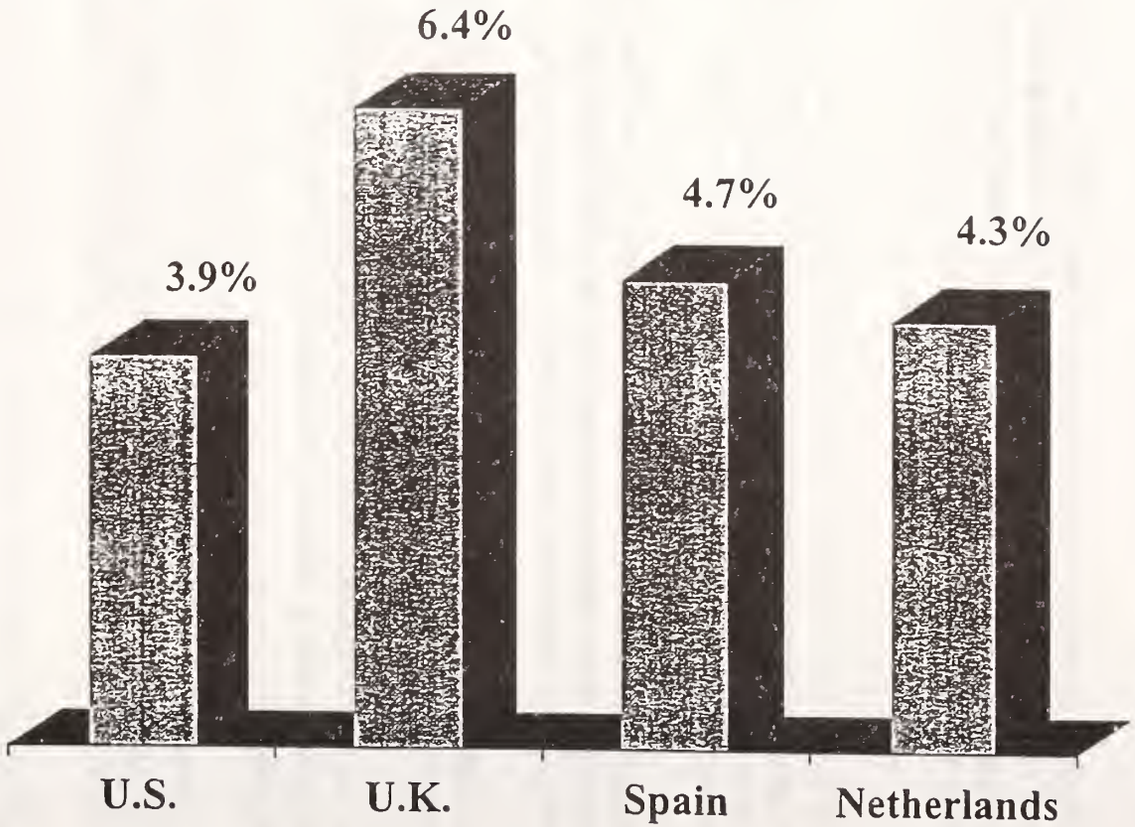
- This bill would significantly reduce revenues – the source of research funding – to the pharmaceutical industry, slowing innovation and delaying the availability of new medicines for patients.

- This legislation imposes price controls on the most research-intensive industry in the U.S., which has proven that the free market is the most effective way to encourage innovation and the development of new medicines to help and heal patients.

June 23, 1999

Attachment 3

Annual Growth in Pharmaceutical Spending, 1990-1997

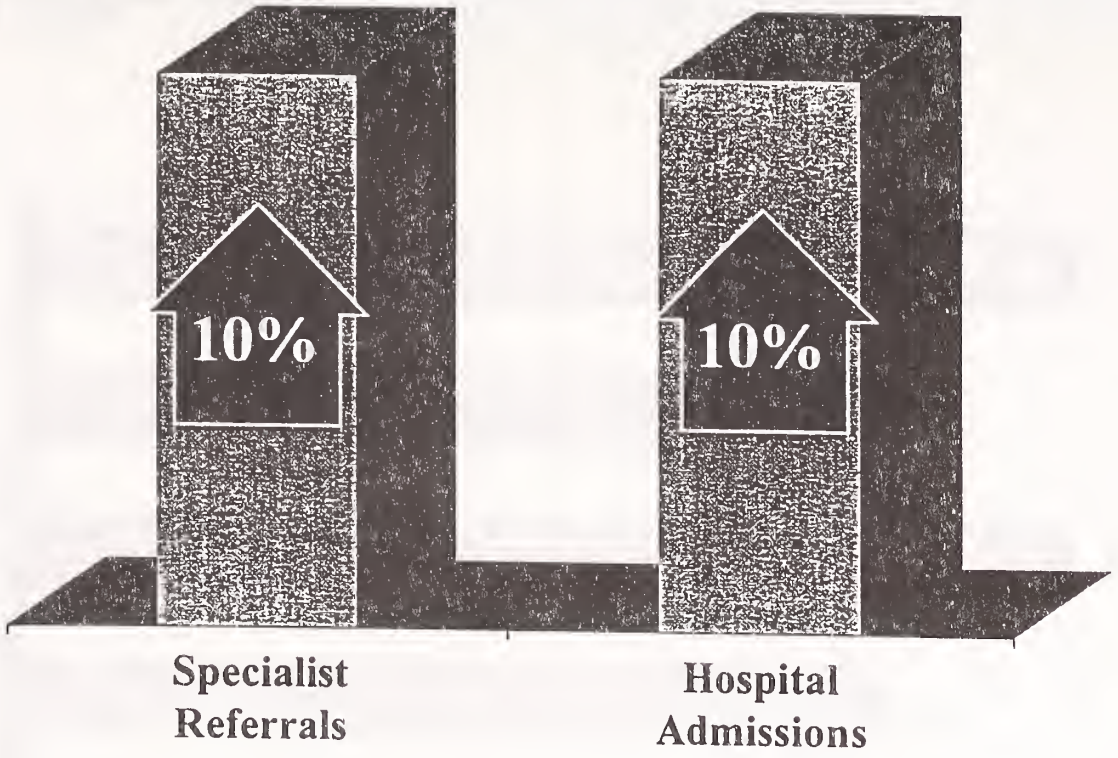


Source: Boston Consulting Group, March 1999

PhRMA

EXHIBIT 4A

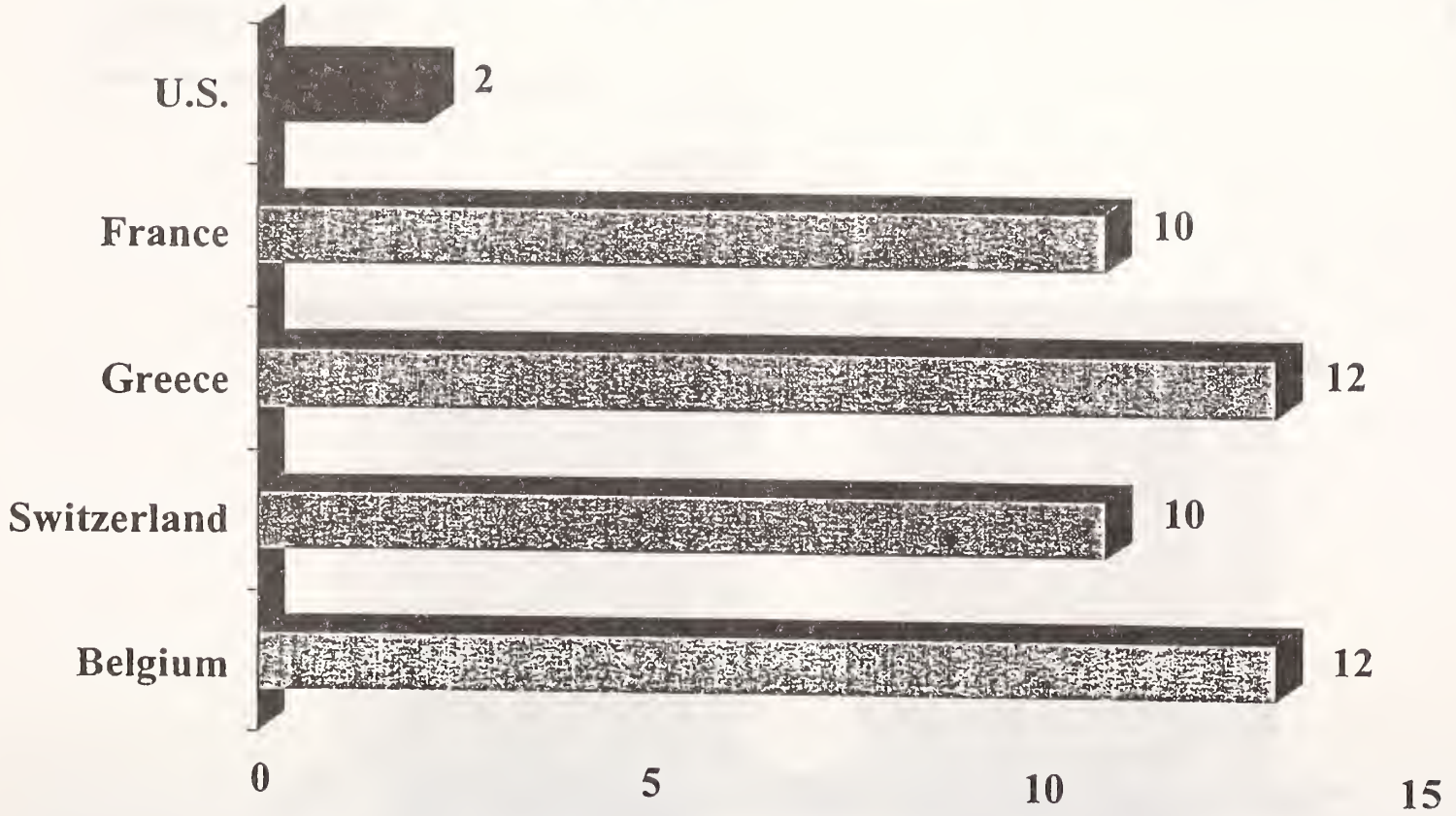
Impact of Pharmaceutical Budgets on Spending in Other Areas, Germany, 1992 - 1993



Source: Boston Consulting Group, March 1999

PhRMA
EXHIBIT 4B

Market Access Delays



Source: Boston Consulting Group, March 1999

PhRMA

EXHIBIT 4C

Percent Reduction in Average Price Per Daily Dose for H_2 Antagonists 1994-1996

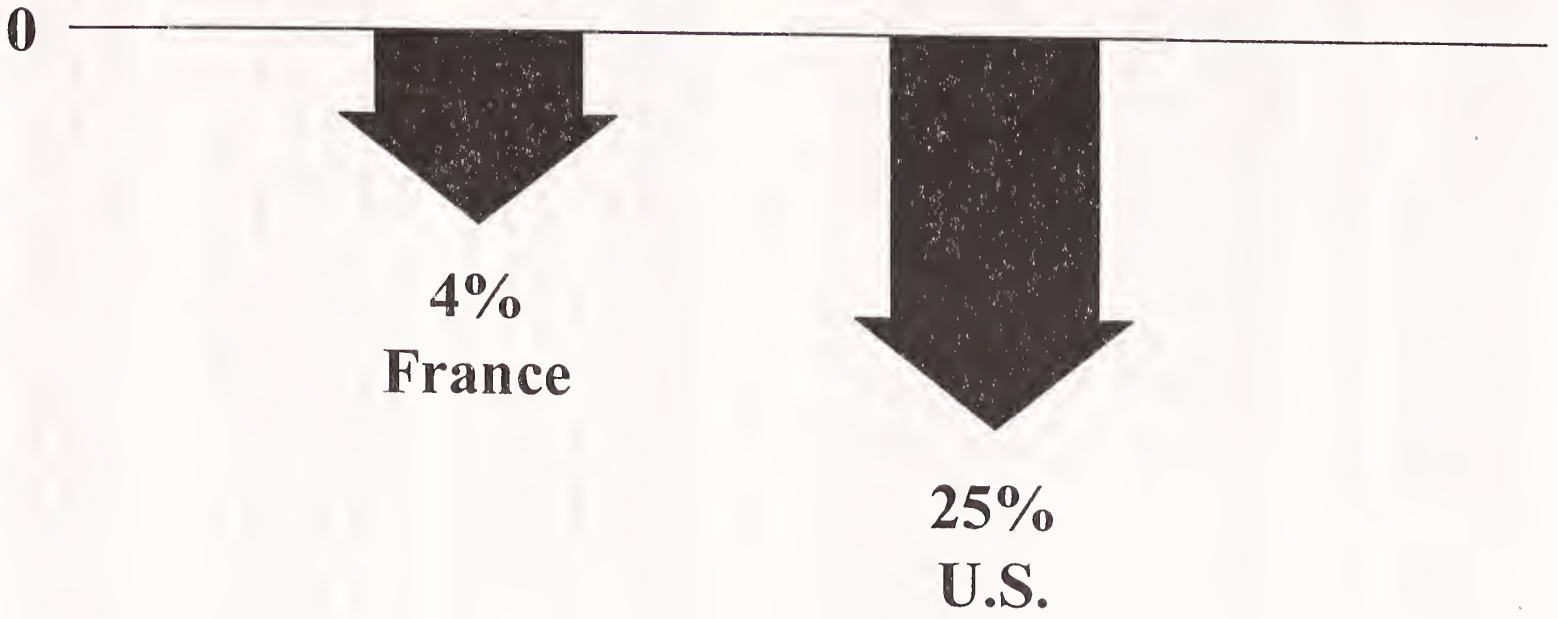


EXHIBIT 4D

Analysis of the Price Control Provisions in S. 841, The Access to Prescription Medications in Medicare Act

S. 841 (H.R. 1495), the Access to Prescription Medications in Medicare Act, contains a number of provisions that would implement direct or indirect government price controls on prescription medicines. These provisions, which are not the only government mandates in the bill, are discussed in detail below.

Payment Limits for Prescription Drugs: Section 2(b) of S. 841

- **The plain meaning of the terms of section 2(b) suggests a sweeping delegation of authority to the Secretary of HHS to determine the amounts paid for Medicare-covered outpatient drugs.** Section 2(b) amends the Social Security Act to provide for payment of prescription drugs under this new legislation, stating that "the amounts paid [for Medicare-covered outpatient drugs] shall be the amounts established by the Secretary pursuant to [new section 1849 as added by S. 841]."

- **Moreover, section 2(b) is explicitly linked to new section 1849 of the Social Security Act, as added by S. 841, and as explained below, new section 1849 specifically requires the Secretary to apply a limit based on a benchmark, a form of indirect price control.** In addition to the plain meaning of the sweeping authority granted by section 2(b), then, its incorporation by reference of new section 1849 imports an indirect price control.

Benchmark for Contracts: Section 3 of S. 841

- **Section 3, which imposes restrictions on the Secretary's ability to contract with entities, is a price control for the following reasons.** When the Secretary is prohibited from entering into a contract unless the private sector supplier offers prices that satisfy government-imposed, government-selected criteria, the government is not permitting private-sector suppliers to determine their price offers based solely on market factors. Instead, the government is intervening into the market using its coercive sovereign powers.

  - It is true that the government-imposed cap that section 3 would establish is derived from prices charged to "large private sector purchasers for such drugs" (an ambiguous term conferring vast discretion on the Secretary). Yet the establishment of a payment limit tied to a benchmark is an exercise of government power, which is wholly unnecessary and inappropriate unless the object and intention are to impose price or payment controls, directly or indirectly.

  - It is critical to recognize that large private-sector purchasers receive a price for a drug based on a complicated set of factors beginning with formulary design and including such other factors as rebates, generic substitution, therapeutic

interchange, prior authorization, copayment rules, and disease management. All of these factors, rather than solely purchasing volume, will determine what large purchasers pay for pharmaceuticals.

- Consequently, the Secretary's benchmark price under the bill is simply not a market-determined price in any way related to a specific drug benefit created for Medicare beneficiaries. Rather, the benchmark imposes a government-administered, arbitrary price limit. Since all the critical parameters of the S. 841 Medicare pharmaceutical benefit (i.e., formulary design, etc.) are determined solely by the Secretary, the private benchmark price will certainly not reflect the price inputs that are necessary for a true market calculation of the Medicare benefit. In every one of the categories listed above, Medicare could require, or bidding entities could create, different methodologies or rules for these factors.

Intrusion of the Government into the Private Market: Section 3 of S. 841

- **Section 3 also clearly intrudes the federal government directly into private-sector transactions, and clearly constitutes a government-mandated limit on the prices charged for individual prescription medicines under this authority**. This section entitles Medicare beneficiaries to buy some drugs (those between the benefit cap and the out-of-pocket limit) "under the contract based on the contract price." The bill thus requires "entities," as a condition for bidding on contracts, to agree to offer contract prices for each individual drug, in private-sector transactions not covered by Medicare, to certain beneficiaries.

June 23, 1999

Access to Prescription Medications in Medicare Act of 1999

What It Is

- S. 841 (H.R. 1495), the Access to Prescription Medications in Medicare Act of 1999, was introduced on April 20 by Senators Edward Kennedy (D-MA) and Jay Rockefeller (D-WV).

What It Does

- The bill would require the Secretary of Health and Human Services (HHS) to contract with pharmacy benefit managers, retail pharmacies, insurers, and other entities to provide a managed prescription drug benefit to Medicare beneficiaries.

- Government contractors would be paid on the basis of capitation, shared risk, or performance.

- Medicare beneficiaries would be responsible for an annual deductible of $200, up to 20% of drug costs between $200-1,700, and 100% of costs between $1,700-4,200. Contracted entities would be responsible for all drug costs once beneficiaries spend $3,000 out-of-pocket.

- Some Medigap plans would be required to include drug coverage, at a level specified by the Secretary of HHS and the National Association of Insurance Commissioners.

- Employers that provide a retiree health plan that covers prescription drugs would be reimbursed by the government for the cost of coverage that meets government requirements.

- Certain low-income Medicare beneficiaries, those with incomes below 135 percent of the federal poverty level, would receive Medicaid prescription drug coverage as a wraparound to this new coverage.

Analysis

- This bill would add a costly new component to the Medicare fee-for-service program, which many Members of Congress, policymakers, and experts believe needs to be modernized to preserve its solvency and improve its benefits.

- The legislation establishes price controls on prescription medicines: The Secretary would establish payment for prescription drugs provided to Medicare beneficiaries and payment would be benchmarked to large private-sector plans. Such an approach is shortsighted because it reduces the incentives for innovative pharmaceutical

Attachment 6

companies to develop new medicines. And for those drugs used almost exclusively by seniors, price and payment controls have an especially draconian impact on research incentives.

- As structured, the bill would divorce the proposed prescription drug benefit from the rest of Medicare. When more integrated, coordinated care is seen as state-of-the-art medicine, such a carve-out runs contrary to the best interest of patients.

- The bill's benefit structure has one huge hole in the middle. Patients with drug costs below $4,200 could be responsible themselves for as much as nearly 70% of the cost of their prescription medicines.

- The proposed legislation is <u>not</u> a private-sector approach – it is simply a new, big government program, through hired hands. HCFA would be given sweeping new authority to regulate pharmacies, pharmacy benefit management companies, insurers, and pharmaceutical manufacturers. As the experience with the Medicare+Choice program has shown, HCFA is stretched beyond its capacity. Many believe it lacks vital expertise, and has not been able to perform its functions effectively.

- Approximately 65 percent of seniors already have some form of coverage for prescription medicines – for example, through Medicaid, Medicare+Choice plans, employee retiree plans, or Medicare supplemental insurance (Medigap). This legislation could displace these existing sources of coverage, adding to the cost of the program.

June 23, 1999

Responses to Questions Submitted by Senator Jeffords

1. *Why are American consumers forced to foot the bill for the research and development of drugs that are sold all over the world at lower prices?*

   It is an oversimplification to say that drugs are always less expensive in other countries. The interaction between different health care systems, prescribing patterns, national economies, and exchange rates (just to name a few relevant factors) is very complex; comparing different countries' prices is thus very difficult and thus often leads to erroneous conclusions.

   Many innovative prescription medicines are more expensive in the United States than in many other countries. In contrast, many generic prescription medicines are more expensive outside the United States. More often than not, any lower prices abroad for newer medicines primarily reflect foreign price controls. We oppose such government price controls, which are unfair to American investment in research and development and to American consumers. We are making some progress in our efforts to have other nations remove, or at least reduce, price controls, as in Germany and Japan.

   In no event would importing these price controls into the United States be the right answer. Price controls hurt patients by reducing the incentive to invest in discovering and developing new medicines. A better strategy would be to encourage other countries to eliminate their own price controls and adopt a market-based system that rewards health plans and providers for providing affordable care and manufacturers for developing innovative new medicines.

   Moreover, it is misleading to say that American consumers "foot the bill" for research. The American system does reward investment in research on and development of new medicines and as a result, the U.S. leads the world in the discovery of new medicines. It is not accurate, however, to say that American consumers solely support research. Whenever and wherever an innovative prescription drug is sold, that purchase helps fund ongoing research and development – which benefits American patients and the U.S. economy.

2. *Are Americans paying higher prices for drugs even when they are developed in other countries? In other words, are U.S. consumers paying for the research and development costs of drugs even if they are developed abroad?*

   The pharmaceutical industry is a global one and it is very difficult to state with absolute finality where a drug is developed. For example, a Swiss-based company may discover a promising compound in a research laboratory located in the United Kingdom, but decide to pursue development in the United States because of the presence of outstanding academic health

centers capable of overseeing the necessary clinical trials. The company may also choose to conduct clinical trials in the United States because the U.S. Food and Drug Administration (FDA) is the gold standard in drug regulation, ensuring both timely and efficient regulation. In addition, the company may decide to conduct an additional trial in a developing nation because the population is highly likely to use the medicine. Such a hypothetical case illustrates the difficulty of claiming that a drug is developed in the U.S. or abroad – the line is simply too fuzzy.

In any case, as was stated in the response to question one, every consumer, wherever he or she lives, helps offset the cost of research on and development of new drugs. The pharmaceutical industry is a global one and most prescription medicines are global.

3. *Your industry has argued that price controls would result in a reduction in research and development, yet you spend a very high percentage of R&D on so-called "me-too" drugs. Why are senior citizens paying such high drug prices to help develop new me-too drugs?*

"Me-too" drugs are a myth. The idea that companies invest in research and development to discover "me-too" products that add no new value for any patients ignores the reality of drug discovery and the individuality of patients.

First, thousands of scientists at pharmaceutical companies are vigorously pursuing the discovery and development of new medicines. An example is instructive. The understanding of the protease enzyme's role in the replication of human immunodeficiency virus (HIV) was integral to developing medicines to fight AIDS. This scientific discovery spurred research and several companies simultaneously dedicated themselves to translating this knowledge into medicines. None of them knew when their drug would be ready for market or whether they would be first or last. As it happens, several innovative companies introduced protease inhibitors within the space of a few months – not because they were copying each other, but because each company pursued a different, promising path. As a result, the several different protease inhibitors on the market are included in the very successful "cocktails;" each benefiting different patients with HIV and AIDS by dramatically extending and improving their lives.

Second, competition among innovative medicines benefits patients by promoting price competition. When there are numerous drugs in the class, they are likely to compete vigorously for patients, both on cost and quality. Moreover, the development of multiple drugs that can compete in a therapeutic class paves the way for more generic competition in the future. Third, innovation is often incremental. The second drug in a class may be slightly different from the first and the third slightly different from the second.

The sixth drug, however, may represent a true breakthrough. If we discourage research on a drug because there are already existing therapies for that disease, we may preclude the discovery and development of a cure.

Senator James M. Jeffords
Statement on Medicare Prescription Drugs – DrugGap Plan
Senate Finance Committee Hearing
June 23, 1999

Good morning Mr. Chairman. Thank you for holding this hearing on one of the most important issues facing our seniors today.

We are all aware that prescription drug costs continue to grow at an alarming rate. Many seniors are having to spend greater and greater portions of their fixed incomes on prescription drugs that they need to live. This increase in costs is driven not only by price increases, but also by seniors taking more advantage of the benefits of new breakthrough drugs that control existing illnesses and prevent new ones.

That is why I am committed to working as hard as I can to see that any Medicare reform proposal considered by this Committee includes a prescription drug benefit. In my opinion, it does not make sense to reimburse hospitals for surgery, but not provide coverage for the drugs that might prevent surgery. Research and development of prescription drugs have come a long way since Medicare was originally enacted in 1965. New treatments are discovered every day that offer the potential to allow seniors to live longer, healthier lives. Today, drugs are just as important, and in many cases more important, than hospital visits.

This is a basic coverage problem that we must address as we modernize the Medicare program, and it is one of my top priorities. Ideally, it should be part of broad Medicare reform. But even if we are not able to achieve broad reform in the Medicare program this year, we must at least do something to address this basic need for seniors. The most recent data available indicate that as many as thirty-five percent of all seniors have no insurance coverage for prescription drugs. That number is too high, and we must find a way to help those uninsured seniors get access to the drugs that they need.

That is why I am developing a legislative proposal to address this issue separate and apart from broad Medicare reform. It is clear that this problem is felt most profoundly by seniors whose incomes are too high to receive Medicaid or other supplemental benefits, yet do not have enough income to purchase a Medigap policy that covers prescription drugs. These are the most vulnerable seniors who can least afford to purchase the drugs that are prescribed for them, yet who are forced to pay the highest prices.

My legislation, which I plan to introduce this summer, will target the most needy seniors. It will provide insurance coverage for prescription medicines for seniors that do not qualify for Medicaid or other supplemental drug coverage. This new "DrugGap" policy will be offered at no cost to low income seniors, but will also be available for purchase by all seniors as a new, low-cost means to access the favorable prices that large purchasers, such as HMOs, can demand.

The proposal I am developing will also include reforms of the Medigap system that will make the Medigap policies operate more efficiently. This will mean implementing some much-needed reforms in order to address the dynamic health care concerns that seniors face. By employing some reasonable structural and payment reforms in the Medigap system, I believe we can offer prescription drug coverage to those seniors who need it by using a small portion of the budget surplus. By reforming Medigap, we will give all seniors access to reasonable prices for the drugs that they need.

Mr. Chairman, this is one approach that I hope other members of this Committee will consider supporting, but it is not the only thing we can do to address this pressing issue. In the coming weeks, I intend to concentrate my efforts on finding other ways to make it easier for Vermonters, and all seniors, to afford prescription drugs.

SENATOR TIM JOHNSON

Statement to the Senate Finance Committee

"Prescription Drug Fairness For Seniors Act of 1999"
S. 731/H.R. 664

June 23, 1999

Mr. Chairman, Senator Moynihan and Members of the Finance Committee, thank you for allowing me to submit my statement in relation to todays hearing on Medicare prescription drug benefits.

A tremendous amount of discussion has been taking place over the issue of providing Medicare beneficiaries with more affordable prescription drug coverage.

On March 25th, I joined my colleague from Massachusetts, Senator Edward Kennedy, by introducing the "Prescription Drug Fairness for Seniors Act of 1999" (S.731). We currently have the support of ten of our colleagues, including Senators Daschle, Dodd, Dorgan, Feingold, Hollings, Inouye, Leahy, Kerry, Wellstone, and Bingaman.

Earlier this year Congressman Tom Allen was joined by Congressmen Jim Turner, Marion Barry, Henry Waxman, and sixty-one of their colleagues when they introduced the House companion bill, H.R. 664. The House bill currently has 114 cosponsors.

Why we need the Prescription Drug Fairness For Seniors Act of 1999 to reduce costs of prescription drug prices

Our legislation addresses the critical issue facing older Americans - the high cost of prescription drugs. Studies have shown that older Americans spend almost three times as much of their income on health care than those under the age of 65. (21% of older Americans versus 8% of those under age 65).

According to statistics, Americans age 65 or older make up 12% of the population but consume 35% of all prescription drugs. At present, 35% of the Medicare population of nearly 40 million people have no prescription benefits from any source. And as we know, Medicare, a federal insurance program, does not provide a prescription drug benefit (except for coverage of a few selected outpatient drugs).

Therefore, while Medicare beneficiaries make up the largest segment of the population that consumes prescription drugs, they do not have access to the low prescription drug costs, as do the drug manufacturer's most "favored customers", such as large insurance companies, HMO's and the federal government.

Even more alarming is the fact that seniors and others who buy their own prescription drugs, are forced to pay over twice as much for their drugs as are the drug manufactures' most favored customers. One in five older Americans takes at least five prescription drugs a day. About 2.2 million elderly Americans pay more than $100 *a month* for medication.

How the "Prescription Drug Fairness For Seniors Act of 1999" will help Medicare beneficiaries

Our approach would simply allow Medicare beneficiaries the same fair access to lower prescription drug costs that drug companies offer to their most "favored" customers. The "Prescription Drug Fairness for Seniors Act" will protect senior citizens from drug price discrimination and make prescription drugs available to Medicare beneficiaries at substantially reduced prices.

The legislation achieves these goals by allowing pharmacies that serve Medicare beneficiaries to purchase prescription drugs at the low prices available to the drug manufacturers most favored customers, such as the federal government and large HMOs.

Since drug prices presently paid by favored buyers are approximately half the retail prices paid by senior citizens, participating pharmacies will be able to pass on large cost savings to senior citizens.

The Prescription Drug Fairness For Seniors Act will allow pharmacists to use the existing pharmaceutical distribution system and not create a new federal bureaucracy. Equally important, our legislation will not require any new federal government spending.

Estimated to reduce prescription drug prices for seniors by over 40%, our bill will help those seniors who often times have to make devastating choices between buying medications or food! Choices that no senior citizen should be forced to make! A senior citizen spending $150 a month on prescription drugs could save over $700 annually under the legislation.

Support for our proposal is building

The response that we are receiving from organizations who support our bill is overwhelming. We are continuing to work to raise the visibility of the outrageously high cost of prescription drugs for seniors and discuss how our bill can help reduce medication cost for Medicare beneficiaries. I am very pleased that the following groups have endorsed our legislation.

American Federation of State, County and Municipal Employees (AFSCME)
Consumer's Federation of America
Custer County Coalition on Aging (South Dakota)
Families USA
Friends Committee on National Legislation
Gray Panthers
National Committee to Preserve Social Security and Medicare
Public Citizen
National Council of Senior Citizens
New England Coalition of State Councils on Aging
Service Employees International Union (SEIU)
TREA Senior Citizens League
United Auto Workers (UAW)
119th Legislature of the State of Maine

Additionally, the American Association of Retired Persons (AARP), offered their support for our efforts on this critical issue.

Support is growing for our prescription drug legislation in my home state of South Dakota too. Within the last month alone, I have received "unsolicited" petitions from South Dakotans in several communities across the state, all signing a petition in strong support of the Prescription Drug Fairness For Seniors Act of 1999.

In just the last couple months alone, whether it be from town hall meetings that I've held in my state on this issue or from personal letters and phone calls, several hundred of my constituents have contacted me to express their support for our efforts, often times sharing their personal stories about lack of access to affordable medication. This kind of grassroots support that the bill has generated is quite unique and I think indicates how critically important this issue is to not only South Dakotans, but millions of Americans across the country as well.

Pharmaceutical Industry Allegations

Research and development of new drug therapies is an important and necessary tool towards improving quality of life. But due to the high price tag that often accompanies the latest drug therapies, seniors are often left without access to these new therapies, and ultimately, in far too many instances, without access to medication at all.

Meanwhile, the pharmaceutical industry enjoys significantly higher profit margins (reaching nearly 29%) than the average manufacturer of other branded consumer goods (which are approximately 10.5%). Overall profits of major drug manufacturers are expected to grow by about 25% in 1999, whereas Medicare beneficiaries are expected to receive a cost-of-living-adjustment (COLA) of less than 3% in their Social Security benefits.

Pharmaceutical Research and Manufacturer's of America (PhARMA), has been waging an all out campaign in opposition of our proposal which includes recent organized mailings to Members of Congress with literature critical of our bills.

I would like to respond to several of the industry's allegations. First, the industry claims that our legislation extends price controls to the pharmaceutical industry. The Prescription Drug Fairness for Seniors Act does not impose price controls on the pharmaceutical industry. Instead, the legislation ends price discrimination. Under the legislation, companies can set their best price at whatever level they want. The goal of the bill is to allow senior citizens access to prescription drugs at these same low prices.

Second, the Industry claims that our legislation will force the pharmaceutical industry to reduce research and development expenditures. However, historically, there is no evidence to support the industry's claim that preventing pharmaceutical companies from overcharging for their products reduces research. In 1984, Congress passed the Hatch-Waxman Act, which increased the availability of generic drugs and provided more competition for brand name drugs. This legislation did not reduce innovation in the pharmaceutical industry. Indeed, according to industry data, over the next five years pharmaceutical companies more than doubled their investment in research and development.

In 1990, Congress passed legislation that created the Medicaid drug rebate, requiring drug companies to reduce their prices for drugs sold to the Medicaid program. This legislation did not reduce innovation in the pharmaceutical industry, however. Since 1990, pharmaceutical companies again more than doubled their spending on research and development, from $8.4 billion in 1990 to $18.9 billion in 1997.

Third, the pharmaceutical industry asserts that our legislation would not allow them to be able to afford to pay for high levels of research and development. There is no support for the industry's assertion that it could not afford its research and development budget if the legislation were enacted. The pharmaceutical industry spends $11 billion annually on advertising and marketing. It also makes $26.2 billion annually in profits. Its profit margin is 28.7%, nearly three times higher than the profit margin of other manufacturers of branded consumer goods. Even if the legislation had the effect of reducing industry revenues, the industry could maintain or even increase its spending on research and development by reducing its profit margin or cutting back on its advertising and marketing expenses. Current industry spending on research and development is $17 billion.

Nobody is saying that the pharmaceutical industry cannot make profits. But profits at the expense of our older Americans -- that is just plain wrong.

Finally, the pharmaceutical industry claims that our bill does not guarantee lower prices because pharmacies, not drug companies, are responsible for the high retail markups paid by senior citizens. At the retail level, the pharmacy market is highly

competitive. Therefore, if consumers are unhappy with the prices charged at one retail outlet, they can buy their prescription drugs at a different outlet. This competitiveness guarantees that pharmacies will pass on to senior citizens the benefits of any lower prices for prescription drugs.

Furthermore, studies conducted by the (Minority Staff) House Government Reform and Oversight Committee have found that the while the average retail price differential for prescription drugs paid by senior citizens versus those paid by drug companies "most favored customer" is approximately 100%, pharmacy markups only account for 22% of this differential. This indicates that it is drug company pricing policies, not pharmacies, that are responsible for the high prescription drug prices paid by seniors.

Conclusion

It is anticipated that Congress will consider adding prescription drug coverage to Medicare. It is expected that any such discussion will take place as part of the larger discussion on potential reforms to Medicare, as evident by the Finance Committee's previous hearings this month and last. However, one of the most difficult challenges of this debate will be the funding mechanism for such a broad benefit plan for all Medicare beneficiaries.

The Prescription Drug Fairness For Seniors Act of 1999 is not intended to be the magic bullet that is going to solve all of our problems with providing affordable medications to our seniors, but it is a solid first step towards restoring the access to affordable medications for our senior citizens and a necessary tool towards improving their quality of life. A step that could reduce prescription drugs for Medicare beneficiaries by as much as 40%, helping those seniors who often times have to make devastating choices between buying medications or food.

While Congress debates the prospect of creating an overall Medicare benefit to provide prescription drug coverage, I believe our legislation is an immediate first step towards achieving our desired goal -- access to lower priced prescription drugs for Medicare beneficiaries. Furthermore, I believe our bill would not only be a crucial first stride towards this goal but would also work to compliment any overall Medicare benefit plan. I look forward to working with my colleagues and the Administration on this critically important issue in the months to come. Thank you.

PREPARED STATEMENT OF MARTHA A. MCSTEEN

GOOD MORNING. I AM MARTHA McSTEEN, PRESIDENT OF THE NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE, A GRASSROOTS EDUCATION AND ADVOCACY ORGANIZATION WITH ABOUT FIVE MILLION MEMBERS AND SUPPORTERS AROUND THE COUNTRY. THANK YOU FOR THE OPPORTUNITY TO SHARE WITH THE COMMITTEE THE VIEWS OF NATIONAL COMMITTEE MEMBERS ON THE ISSUE OF PRESCRIPTION DRUGS AND MEDICARE.

IN 1965, MEDICARE REFLECTED THE CUSTOMARY PRACTICE OF MEDICINE, WITH ITS EMPHASIS ON HOSPTIAL-BASED OR PHYSICIAN-PROVIDED CARE. TODAY, THOSE HOSPTIALS AND PHYSICIANS INCREASINGLY RELY ON PHARMACEUTICALS TO PREVENT OR REVERSE THE EFFECTS OF ILLNESS. SOME OF THE PRESCRIPTION DRUGS ARE SUBSTITUTIONS FOR INVASIVE PROCEDURES. IN OTHER CASES, THE PRESCRIPTION DRUGS OFFER RELIEF THAT PREVIOUSLY WAS NOT AVAILABLE. THE CENTERS FOR DISEASE CONTROL EXAMINED 1992 DATA AND FOUND THAT 64 PERCENT OF ALL MEDICAL ENCOUNTERS RESULT IN THE PRESCRIPTION OF MEDICATION. SO LONG AS PRESCRIPTION DRUGS ARE AVAILABLE TO SOME, BUT NOT ALL SENIORS, THERE WILL BE A SUBSTANTIAL BARRIER TO NECESSARY HEALTH CARE FOR SENIORS.

AS YOU KNOW, A LARGE PORTION OF THE AVERAGE SENIORS' INCOME IS SPENT ON OUT-OF-POCKET HEALTH CARE AND ONE SIGNIFICANT ASPECT OF THAT STEMS FROM THEIR PRESCRIPTION DRUG COSTS. THE AVERAGE SENIOR TAKES FOUR PRESCRIPTIONS DAILY AND FILLS AN AVERAGE OF 18 PRESCRIPTIONS A YEAR. ACCORDING TO THE SPRY FOUNDATION, SENIORS SPEND APPROXIMATELY THREE TIMES AS MUCH ON OUT-OF-POCKET EXPENSES AS THE UNDER 65 POPULATION, DUE SUBSTANTIALLY TO THE FACT THAT JUST OVER ONE-THIRD OF SENIORS DO NOT HAVE INSURANCE COVERAGE FOR OUT-PATIENT PRESCRIPTION DRUGS. MEDIGAP POLICIES ARE VERY EXPENSIVE AND HAVE LIMITED PRESCRIPTION DRUG COVERAGE. MONTHLY DRUG BILLS RUNNING INTO THE HUNDREDS OF DOLLARS ARE NOT UNCOMMON SINCE THE MAJORITY OF BENEFICIARIES HAVE SOME CHRONIC HEALTH PROBLEM THAT REQUIRES ONGOING TREATMENT WITH PRESCRIPTION DRUGS.

MR. CHAIRMAN, MEMBERS OF THE NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE STRONGLY SUPPORT AND VERY MUCH NEED DRUG COVERAGE IN THE BASIC MEDICARE BENEFIT.

AS IMPORTANT AS PRESCRIPTION DRUG COVERAGE IS, MR. CHAIRMAN, MEDICARE BENEFICIARIES ALSO WANT SOMETHING DONE ABOUT THE COST OF THOSE PRESCRIPTION DRUGS. THE COSTS OF PRESCRIPTION DRUG PRICES HAVE RISEN MORE THAN 50 PERCENT SINCE 1989. BUT SENIORS' OUT OF POCKET DRUG COSTS ARE ALSO HIGH BECAUSE THOSE WITHOUT PRESCRIPTION DRUG COVERAGE LACK CLOUT IN THE RETAIL MARKET. ACCORDING TO A RECENT STANDARD AND POORS REPORT, DRUG MANUFACTURERS PROVIDE LARGE PURCHASERS WITH SIZEABLE DISCOUNTS ON THE MOST POPULAR PRESCRIPTION DRUGS. THEY MAKE UP THE LOST REVENUE BY INCREASING THE RETAIL PRICE OF PHARMACEUTICALS FOR THE PRIVATE MARKET. ACCORDING TO A 1998 STUDY BY THE HOUSE COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT, THE SAME MANUFACTURERS EVEN OFFER BETTER PRICES TO PURCHASERS OUTSIDE OF THE U.S. AND PRACTICE PRICE DISCRIMINATION AGAINST SENIORS. PHARMACEUTICAL MANUFACTURERS ARE ABLE TO DO THIS BECAUSE SENIORS NEED THESE MEDICINES, AND MANY CASES, ARE WILLING TO GIVE UP GROCERIES AND OTHER NECESSITIES TO PURCHASE THEM.

THE HIGH PRICE OF PHARMACEUTICALS IS A HEAVY BURDEN FOR THE MAJORITY OF SENIORS WHO ARE ON LOW, FIXED INCOMES. THIRTY PERCENT OF ALL SENIORS HAVE ANNUAL INCOMES BELOW $10,000. SEVENTY-FIVE PERCENT OF SENIORS HAVE ANNUAL INCOMES BELOW $25,000. AND YET, THE AVERAGE SENIOR PAYS HALF OF THE COST ASSOCIATED WITH THEIR PRESCRIPTIONS. BY WAY OF COMPARISON, THE AVERAGE PERSON UNDER AGE 65 PAYS ONLY 34 PERCENT.

IT IS OFTEN MENTIONED THAT THE MAJORITY OF SENIORS ALREADY HAVE PRESCRIPTION DRUG COVERAGE. IT IS IMPORTANT TO EXAMINE WHAT THAT COVERAGE REALLY CONSISTS OF. FOURTEEN PERCENT OF BENEFICIARIES HAVE DRUG COVERAGE BECAUSE THEY PURCHASE MEDIGAP. ANOTHER EIGHT PERCENT GET COVERAGE FROM MEDICARE

HMOs. ANOTHER 16 PERCENT ARE COVERED UNDER MEDICAID, ABOUT 29 PERCENT HAVE RETIREE HEALTH INSURANCE BENEFITS THAT OFFER DRUG COVERAGE. THIS INEFFICIENT PATCHWORK OF PLAN COVERAGE MEANS VARIATIONS IN COST, FEES AND FINANCIAL LIMITS ON PRESCRIPTION DRUG COVERAGE. WITH RETIREE INSURANCE COVERAGE ON THE DECLINE, HMOs UNCERTAIN ABOUT THEIR PARTICIPATION IN MEDICARE AND MEDIGAP PREMIUMS JUMPING BY 20 PERCENT OR MORE ANNUALLY, MEDICARE BENEFICIARIES NEED THE ASSURANCE OF A DRUG BENEFIT IN THE BASIC MEDICARE PACKAGE. MEDICARE IS ABOUT TO BE HIT WITH A WAVE OF MEDICARE+CHOICE PLANS ANNOUNCING MAJOR CUTBACKS IN DRUG AND OTHER EXTRA BENEFITS. WHILE ABOUT A SIXTH OF SENIORS IN HMOs HAVE DRUG COVERAGE, THEY WILL BE SHOCKED BY THE SIZE OF UPCOMMING BENEFIT REDUCTIONS. MANY OF THE INDIVIDUALS WHO NEED IT MOST ARE MEMBERS OF THE NATIONAL COMMITTEE. LET ME TELL YOU ABOUT SOME THEM.

- THERE IS ARNETTA FERN BAKNER, FROM LAFEYETTE, IN, WHO IS 75 YEARS OLD AND A WIDOW FOR THE LAST NINE YEARS. SHE IS DISABLED AS A RESULT OF LIPHODEMIA IN HER LEFT ARM, SHE HAS HAD SEVERAL MAJOR SURGERIES AND TAKES MEDICATION FOR HEART DISEASE. HER INCOME IS $940 A MONTH. AFTER PAYING FOR HER SUPPLEMENTAL HEALTH INSURANCE, HER MEDICATIONS, HER LIFE INSURANCE, REAL ESTATE TAXES, HER UTILITIES AND HOUSEHOLD EXPENSES, SHE HAS $15 DOLLARS A MONTH TO COVER FOOD, GASOLINE, GIFTS FOR HER GRANDCHILDREN AND OTHER EXPENSE THAT CROP UP. HER MEDICATIONS ARE CURRENTLY $187 A MONTH.
- THERE IS ROBERT JOHNSON, FROM MELBOURNE, FL WHO IS 78. HE SUFFERS FROM HYPERTENSION AND ARTERIAL ARTHYMIA. SEVERAL YEARS AGO HE HAD QUADRUPLE BYPASS SURGERY. HE CONTINUES TO TAKE SIX DIFFERENT DRUGS PRESCRIBED BY HIS CARDIOLOGIST, THE MOST EXPENSIVE OF WHICH, ZOCOR, COSTS $1,259 A YEAR. HIS TOTAL OUT-OF-POCKET PHARMACEUTICAL COSTS ARE APPROXIMATELY $2,315 A YEAR, NOT COUNTING THE 6 VITAMINS PRESCRIBED BY HIS PHYSICIAN AND THE $4,928 HE PAYS IN PREMIUMS FOR SUPPLEMENTAL MEDIGAP COVERAGE AND FOR PRIVATE LONG-TERM CARE INSURANCE THAT HE PURCHASED. HIS OUT-OF-POCKET HEALTH RELATED EXPENDITURES ADD UP TO MORE THAN $7,200 A YEAR.

AS A FIRST LEGISLATIVE STEP TOWARD ENDING THIS HODGEPODGE AND EXPENSIVE SYSTEM, THE NATIONAL COMMITTEE SUPPORTS S. 731, THE PRESCRIPTION DRUG FAIRNESS FOR SENIORS ACT. THIS LEGISLATION WOULD PROVIDE MEDICARE BENEFICIARIES WITH PURCHASING POWER SIMILAR TO THAT OF MANAGED CARE ORGANIZATIONS, STATE MEDICAID AGENCIES, THE PUBLIC HEALTH SERVICE AND THE VETERANS ADMINISTRATION. AS A BLOCK OF ONE OF LARGEST PURCHASERS OF PHARMACEUTICALS, MEDICARE BENEFICIARIES SHOULD GET THE SAME DISCOUNTS AS OTHER BULK BUYERS. ENDING THE PRICE DISCRIMINATION AGAINST MEDICARE BENEFICIARIES IS MORE THAN JUST AN EQUITY ISSUE—IT IS THE FIRST STEP TOWARD MAKING DRUGS AND THUS THE MEDICARE DRUG BENEFIT MORE AFFORDABLE. THE PRESCRIPTION DRUG FAIRNESS FOR SENIORS ACT WILL PROVIDE HELP TO BENEFICIARIES STRUGGLING TO MAKE ENDS MEET.

THE NATIONAL COMMITTEE CALLS ON MEMBERS OF THIS BODY TO PASS, BY THE END OF THIS CONGRESS, A PRESCRIPTION DRUG BILL THAT MAKES DRUGS AFFORDABLE TO MEDICARE BENEFICIARIES AND INCLUDES A DRUG BENEFIT IN THE BASIC MEDICARE PACKAGE. THE BASIC DRUG BENEFIT MUST BE UNIVERSAL, INCLUDE A BROAD SPECTRUM OF FINANCING ELEMENTS INCLUDING BENEFICIARY CONTRIBUTIONS AND GENERAL REVENUE CONTRIBUTIONS AND UTILIZES MEDICARE'S SIZE TO ACHIEVE VOLUME PRICE DISCOUNTS FOR BENEFICIARIES.

A RANGE OF FINANCIAL OPTIONS SHOULD BE CONSIDERED FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT. THE FY 2000 BUDGET RESOLUTION CREATED, ON A BIPARTISAN BASIS, A RESERVE FUND FOR THE PAYMENT OF PRESCRIPTION DRUGS IN MEDICARE, FINANCED THROUGH AN INCREASE IN TOBACCO TAXES. ACCESS TO THIS RESERVE FUND WAS CONTINGENT UPON THIS COMMITTEE'S PASSAGE OF A MEDICARE SOLVENCY BILL. ACCORDING TO THE AUTHORS OF THE PROVISION, THAT BILL IS REQUIRED TO "SIGNIFICANTLY EXTEND" MEDICARE SOLVENCY "BEYOND ITS CURRENT INSOLVENCY DATE OF 2008." MR. CHAIRMAN, I

SUGGEST THAT THE CURRENT EXTENSION OF MEDICARE SOLVENCY TO THE YEAR 2015, THE GREATEST NUMBER OF YEARS OF MEDICARE SOLVENCY IN PROGRAM HISTORY, MEANS THAT YOU ALREADY HAVE THE "SIGNIFICANT EXTENSION" THAT THE AUTHORS OF THE PROVISION INTENDED. FURTHER, THE FY 2000 BUDGET RESOLUTION CALLS FOR FINANCING THE PRESCRIPTION DRUG BENEFIT WITH A PORTION OF THE PROJECTED ON-BUDGET SURPLUSES, ESTIMATED TO BE MORE THAN $100 BILLION OVER 10 YEARS. THEREFORE, I URGE YOU AND MEMBERS OF THE COMMITTEE TO USE THE DESIGNED MEDICARE RESERVE FUND, FINANCED WITH INCREASED TOBACCO TAXES AND THE SET-ASIDE PORTION OF THE ON-BUDGET SURPLUSES, IN THE FINANCING PACKAGE FOR THE PRESCRIPTION DRUG BENEFIT. OF COURSE, SENIORS DO NOT EXPECT A FREE RIDE AND WILL SUPPORT AN INCREASE IN PART B PREMIUMS TO PAY FOR THE COST OF A PORTION OF THE BENEFIT, SIMILAR TO OTHER BENEFITS UNDER MEDICARE. BECAUSE THE PREMIUM INCREASE IS LIKELY TO BE $20 TO $40 PER MONTH, IT IS MORE IMPORTANT THAN EVER THAT THE LOWER INCOME BENEFICIARIES HAVE 100 PERCENT ENROLLMENT IN QMB AND SLMB.

THE PROGRAM'S BENEFIT PACKAGE NEEDS TO BE MODERNIZED. ONE OF THE MAJOR CHALLENGES FOR MEDICARE OVER THE NEXT TWENTY TO THIRTY YEARS WILL BE PROVIDING CARE FOR THE FIVE PERCENT OF BENEFICIARIES WHO ARE RESPONSIBLE FOR APPROXIMATELY HALF OF THE COST OF THE PROGRAM. THE BENEFIT PACKAGE MUST BE REDESIGNED IN A WAY THAT ADDRESSES THIS DEMOGRAPHIC REALITY. AT THE SAME TIME, THE NATIONAL COMMITTEE IS CONCERNED THAT SENIORS REMAIN FINANCIALLY INDEPENDENT FROM THEIR FAMILIES, PHYSICALLY ACTIVE AND INVOLVED IN THEIR COMMUNITY AS LONG AS POSSIBLE. ACCORDINGLY, WE BELIEVE THAT POLICIES SHOULD BE PUT IN PLACE TO REDUCE AGE-SPECIFIC DISABILITY RATES, WHICH IN TURN WILL LESSEN THE FINANCIAL IMPACT ON MEDICARE.

ONE WAY THIS CAN BE ACCOMPLISHED IS BY ADOPTING A GERIATRIC CASE MANAGER SYSTEM AS AN INTEGRAL PART OF CARE, REGARDLESS OF WHETHER A BENEFICIARY IS IN FEE-FOR-SERVICE OR MANAGED CARE. TOO OFTEN, SENIORS BECOME ILL BECAUSE OF PREVENTABLE CIRCUMSTANCES, SUCH AS INCOMPATIBLE PRESCRIPTIONS OR IMPROPER NUTRITION. GERIATRIC CASE MANAGERS CAN TAKE INFORMATION FROM PATIENTS AND PROVIDERS AND COORDINATE CARE ACROSS AN INTERDISCIPLINARY TEAM, RATHER THAN WAIT UNTIL A BENEFICIARY'S HEALTH DETERIORATES AND REQUIRES DRAMATIC AND EXPENSIVE INTERVENTION. GERIATRIC CASE MANAGERS, SUCH AS THE PROGRAM I AM FAMILIAR WITH AT WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER HAS ENHANCED THE QUALITY OF LIFE FOR BENEFICIARIES AND IS COST-EFFECTIVE. PROGRAMS SUCH AS THIS ONE CAN FREE UP FUNDS FOR OTHER IMPORTANT PRIORITIES, SUCH AS A PRESCRIPTION DRUG BENEFIT.

OTHER CHANGES THAT SHOULD BE MADE WOULD BE OF TREMENDOUS VALUE TO BENEFICIARIES

- FINANCIAL ASSISTANCE FOR SENIORS UP TO 150 PERCENT OF POVERTY WILL ENSURE THAT COST IS NOT A BARRIER TO ACCESS.
- INDEXING THE ACTUARIAL VALUE OF THE BENEFIT IS ESSENTIAL TO KEEP PACE WITH INFLATION.
- STOP LOSS COVERAGE IS NECESSARY FOR THOSE WITH HIGH DRUG COSTS.

OTHER CHANGES NEED TO BE MADE TO THE FINANCING TO REFLECT CHANGES IN PRIVATE PLANS. METHODS USED BY LARGE PURCHASERS, SUCH AS DIFFERENT COPAYS OR DEDUCTIBLES BASED UPON THE SELECTION OF GENERIC OR NAME-BRAND PHARMACEUTICALS AND UTILIZATION REVIEW OF THE PRESCRIBING TRENDS SHOULD BE CONSIDERED. SENIORS WHO ARE FINANCIALLY ABLE ARE WILLING TO CONTRIBUTE THEIR FAIR SHARE TOWARD THE COST OF THE BENEFIT. DEDUCTIBLES OF $200 ANNUALLY AND CO-PAYMENTS NO GREATER THAN 20 PERCENT FOR BRAND-NAME DRUGS ARE TWO EXAMPLES.

BUT LET ME BE CLEAR. THE NATIONAL COMMITTEE IS OPPOSED TO ATTEMPTS TO INCOME-RELATE THE OUT-OF-POCKET COSTS OF DRUG COVERAGE, JUST AS WE ARE OPPOSED TO MEANS-TESTING THE PROGRAM ITSELF. THE NATIONAL COMMITTEE RECOGNIZES THAT MANY MEMBERS OF THIS BODY HAVE CALLED FOR A GREATER FINANCIAL CONTRIBUTIONFROM BENEFICIARIES WITH HIGHER INCOMES. OUR POSI-

TION IS THAT THIS HAS BEEN ACCOMPLISHED WITH THE LIFTING OF THE CAP ON THE PAYROLL TAX. ACCORDING TO A LEWIN-VHI STUDY, THE RESULT OF LIFTING THE CAP IS THAT THE TOP 50 PERCENT OF TAXYPAYERS WILL PAY MORE TOWARD MEDICARE THAN THEY WILL RECEIVE IN BENEFITS IN ORDER TO FINANCE BENEFITS FOR THE BOTTOM 50 PERCENT OF BENEFICIARIES. TO GO FURTHER PUTS PUBLIC SUPPORT FOR THE PROGRAM AT RISK.

MISTER CHAIRMAN, THIRTY-FOUR YEARS AGO NEXT MONTH, THE CONGRESS ESTABLISHED MEDICARE AND FORGED AN HISTORIC COMMITMENT WITH AMERICA'S SENIORS AND THEIR FAMILIES—THAT UNIVERSAL, QUALITY, AND AFFORDABLE HEALTH CARE WOULD BE ASSURED FOR THIS NATION'S SENIORS REGARDLESS OF THEIR AGE, INCOME, RESIDENCE OR HEALTH STATUS. WE UNDERSTAND THAT CONGRESS DID NOT INTEND THAT MEDICARE NEVER BE CHANGED; INDEED, WE WHOLEHEARTEDLY SUPPORT CHANGES SUCH AS A PRESCRIPTION DRUG BENEFIT THAT WE ARE CONVINCED WILL DRAMATICALLY IMRPOVE THE HEALTH CARE OF TODAY'S AND TOMORROW'S BENEFICIARIES, AND SAVE MONEY FOR MEDICARE IN THE LONG-RUN.

THE NATIONAL COMMITTEE IS PERSUADED AS WELL THAT A DRUG BENEFIT OFFERS AN OPPORTUNITY TO BRING MEDICARE IN LINE WITH THE WORLD OF MEDICINE TODAY AND REAFFIRM THE COMMITMENT THIS LEGISLATIVE BODY MADE 34 YEARS AGO. CONGRESS IN 1965 RESPONDED TO THE MILLIONS OF SENIORS WHO WERE THEN SHUT OUT OF AMERICA'S HEALTH CARE SYSTEM. TODAY, MILLIONS OF SENIORS AGAIN ARE FAILING TO RECEIVE ADEQUATE CARE BECAUSE OF DRUG COSTS TOO MANY OF THEM SIMPLY CANNOT AFFORD. IT IS TIME AGAIN FOR CONGRESS TO RESPOND. IT IS TIME AS WELL FOR THE PHARMACEUTICAL INDUSTRY TO OFFER COOPERATION AND CONSTRUCTIVE ASSISTANCE INSTEAD OF WHAT FROM ALL INDICATIONS APPEARS TO BE ITS DETERMINATION TO LAUNCH AN AGGRESSIVE CAMPAIGN TO THWART LEGISLATIVE EFFORTS FOR A REMEDY.

LET ME SAY IN CONCLUSION THAT, TO THOSE WHO SUGGEST THAT AMERICA CANNOT AFFORD TO OFFER A PRESCRIPTION DRUG BENEFIT TO ALL MEDICARE BENEFICIARIES, SOCIAL SECURITY AND MEDICARE ALREADY HAVE CONTRIBUTED HEAVILY TO THE ERA OF DEFICIT REDUCTION, WHICH HAS LED TO THE ECONOMIC PROSPERITY WE CURRENTLY ENJOY TODAY. ABOUT A HALF TRILLION DOLLARS IN SOCIAL SECURITY SURPLUSES HAVE BUTTRESSED THE DEFENSE BUILDUP, THE TAX CUTS, AND THE S&L BAILOUT ENACTED BY THIS BODY.

IN THIS DECADE, MEDICARE PROGRAM CUTS HAVE BROUGHT THE PROGRAM IN LINE WITH EXISTING FINANCING. THE SOCIAL SECURITY SURPLUS IS A SIGNIFICANT PART OF THE CURRENT BUDGET SURPLUS, AND IT HAS BEEN USED TO FINANCE OTHER PROGRAMS AS WELL AS REDUCE GOVERNMENT DEBT. MEDICARE SHOULD SHARE OUR CURRENT ECONOMIC PROSPERITY WITH THE ADDITION OF A BENEFIT THAT IS IN KEEPING WITH MODERN MEDICAL PRACTICE.

Can CONGRESS AND THE COUNTRY AFFORD PRESCRIPTION DRUG COVERAGE? THIS BODY AND NATION IN THE PAST HAS EMBRACED AND ACCOMPLISHED FAR LARGER AND FAR MORE COSTLY CHALLENGES. IN THIS CENTURY ALONE, WE COMMITTED OURSELVES AND OUR FORTUNES IN A MONUMENTAL EFFORT FOR VICTORY IN WORLD WAR II; WE INVESTED IN OUR RETURNING SOLDIERS WITH THE HISTORIC GI BILL; WE LINKED CITY TO COUNTRYSIDE AND STATE TO STATE WITH THE INTERSTATE HIGHWAY SYSTEM; WE FINANCED AND FOUGHT AND WON THE COLD WAR; WE SET THE NATION ON A REMARKABLE PATH THAT LIFTED AMERICA INTO SPACE AND PUT MANKIND ON THE MOON. YES, WITH LEADERSHIP AND COMMITMENT, THE CONGRESS AND THE COUNTRY CAN ALSO MAKE SURE AMERICA'S RETIREES—ALL OF THEM—HAVE ADEQUATE CARE. THANK YOU VERY MUCH.

PREPARED STATEMENT OF DR. MORRIS B. MELLION

Mr. Chairman and members of the committee, I am Dr. Morris B. Mellion, Senior Vice President of Health Care Policy and Chief Medical Officer at Blue Cross and Blue Shield of Nebraska.

Today, I am testifying on behalf of the Blue Cross and Blue Shield Association (BCBSA). BCBSA represents the 51 independent Blue Cross and Blue Shield Plans

throughout the nation that together provide health coverage to 73 million Americans. I appreciate the opportunity to testify on prescription drug benefits.

Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage to both working and retired Americans.

- Blue Cross and Blue Shield Plans underwrite and deliver the government-wide Service Benefit Plan under the Federal Employee Health Benefits Program (FEHBP). This plan has been in the federal program since its inception in 1960. It covers over 1.9 million contracts and more than 3.7 million lives. The Service Benefit Plan provides outpatient prescription drug benefits to its members, many of whom are retired.
- BCBS Plans offer health coverage to working Americans through a variety of managed care and indemnity products, including health maintenance organizations (HMOs), preferred provider organizations (PPOs) and point of service (POS) plans. Nearly all of these plans provide prescription drug benefits to their members.
- Collectively, BCBS Plans provide Medicare HMO coverage to more than one million Medicare beneficiaries, making them the second largest Medicare+Choice (M+C) provider in the country. Most of the BCBS M+C plans provide outpatient prescription drug benefits to their members.
- BCBS Plans also provide Medigap coverage, which offers seniors varying levels of protection from Medicare's cost sharing requirements. Three of the 10 standardized Medigap packages include outpatient prescription drug coverage.

Our constant challenge, which Congress will face if they include prescription drug benefits under Medicare, is to provide a meaningful level of coverage for prescription drug costs while keeping premiums as affordable as possible. It is a major challenge and we have a harsh consequence if we fail to structure the right premiums—the customer will not select our products.

In my testimony today, I will address four areas:

- Background on the costs of providing outpatient prescription drug coverage.
- Strategies used by BCBS Plans to manage prescription drug benefits.
- Comments on proposals to mandate that all Medigap policies cover prescription drugs.
- Considerations in adding a prescription drug benefit to Medicare.

I. BACKGROUND ON PRESCRIPTION DRUG BENEFITS

Prescription drugs have significantly increased Americans' life span and contributed to their improved health status in the 20th century. Recognizing the potential for pharmaceuticals to prevent and treat disease, BCBS Plans offer pharmacy benefits to their members. However, the cost of drug benefits is high and accelerating at rates well above those of other benefit costs. As a result, drugs account for a growing share of BCBS Plans' total medical costs and our members' premium dollars. BCBSA expects these costs to continue to grow rapidly.

Historical Trends in Pharmacy Costs:

- From 1993 to 1998, it is estimated that BCBS Plans' aggregate spending on outpatient drugs increased almost 60 percent, from $7.6 billion to $12 billion (on a stable population base). Some Plans have experienced even more rapid growth in pharmacy costs. For example, payments made by one Blue Cross and Blue Shield Plan rose by 26 percent just in 1997 and were expected to rise by another 25 percent in 1998.
- Earlier this year, a large, self-insured customer of BCBS of Nebraska expressed surprise at its rising pharmaceutical costs and requested further analysis. We compared its 1996 and 1998 pharmacy expenditures and found that:
- The average number of prescriptions per member had risen from 8.2 to 9.4;
- The average ingredient cost per brand drug prescription had increased from $43.36 to $57.72;
- The use of generic drugs had declined from 41.95 percent to 38.45 percent; and
- The average annual prescription cost per member had climbed from $188.21 to $319.13.
- Other private insurers have experienced similar increases. In May 1999, the Employee Benefit Research Institute reported that private insurance payments for prescription drugs increased 17.7 percent in 1997, after growing 22.1 percent in 1995 and 18.7 percent in 1996. This growth in prescription drug payments compares with 4 percent or less annual growth in overall private payments for each of these three years.
- For BCBS Plans, aggregate drug costs increased from an estimated 12 percent of total medical costs in 1993 to 14 percent by 1997, while other components remained relatively stable. For some Plans, payments for prescription drugs

now exceed those for inpatient hospitalization. In the broader U.S. private insurance market, analysts estimate that prescription drugs now account for 11 to 14 percent of total medical expenses for most health plans, up from 7 percent just a few years ago.

- Prescription drug costs may be even higher for some health plans, especially those that provide drug benefits to older populations. For example, the Service Benefit Plan under FEHBP, which covers a large number of retired workers, has experienced rapidly escalating prescription drug costs. Today, these costs are approaching 30 percent of total benefit costs.

Factors Contributing to Increased Prescription Drug Spending:

While BCBS Plans use a range of strategies to manage growing prescription drug costs on behalf of their subscribers, spending is being propelled by a number of market and structural forces over which private insurers have little control. Some of the most important forces are the following:

Demographic Trends

As the U.S. population ages, the number of people at risk for chronic and disabling diseases is rising dramatically. The single largest market for prescription drugs is the aging baby boom generation. According to U.S. Census data, the 54-to-64 age group will expand by 59 percent between 1998 and 2010. The drugs used by the middle aged and elderly tend to be expensive and often treat chronic conditions, such as hypertension, high cholesterol, diabetes and arthritis, which require a steady regimen throughout the patient's remaining life.

Rapid Flow of New Drugs to Market

Over the past decade, many new prescription drugs have come to market. One of the most robust measures of the flow of pharmaceutical technology is the annual number of new molecular entities (NMEs) approved by the FDA. NMEs are compounds that have never before been marketed in this country. Over the course of a generation—from the early 1960s to the mid 1990s—the annual number of new molecular entities (NMEs) receiving FDA approval nearly doubled. From an average of 13.7 in the 1960s, annual NME approvals rose to 25.6 in the first half of the 1990s. Since then, the number has nearly doubled again. In the two-year period 1996-1997, the FDA approved a total of 92 NMEs, at an average rate of 46 per year.

Some of these new drugs are "breakthrough" products, which treat diseases and conditions that previously lacked effective therapies. Others are differentiated from older drugs by having less prevalent or severe side effects, or easier dosing forms. Physicians tend to adopt such new technology rapidly. While these new products often provide important clinical benefits, they also increase health insurance premiums.

For example, new immune system drugs have been developed which provide a powerful new treatment for serious ailments like Crohn's disease and arthritis. As a Chief Medical Officer of a health plan, I recognize that no other drug comes close to achieving the same result. Yet, these drugs are very expensive and contribute to premium increases. These are the types of challenges that health plans now face.

The National Institute for Health Care Management (NIHCM), a non-profit, nonpartisan research organization based in Washington, D.C., will soon release a report on trends in pharmacy spending. This report, which was prepared by the Barents Group LLC, examines the growth of retail prescription drug sales. The report found that:

- Over the five year period 1993—1998, prescription drug spending rose from $51 billion to $93 billion, or by 84 percent.
- $27.6 billion, or 65 percent of this $42 billion increase, was associated with new prescription drugs: that is, those approved by the FDA after 1992.
- By 1998, new drugs accounted for $30 billion or 32 percent of retail drug expenditures even though they represented just 17 percent of all prescriptions. In some therapeutic categories, however, new drugs accounted for over half of spending. For example, an estimated 98 percent of the 1998 sales of antihistamines, 68 percent of anti-cholesterol agents, and 51 percent of antidepressants were derived from new drugs.
- In 1998, the average price per prescription of a new drug was $71.49 per prescription, compared with $30.47 for older drugs. However, for some new drugs, the average price per prescription was three to seven times that of the older drug it replaced.

We expect this flow of new drug technology to continue. Over the past two decades, the pharmaceutical industry and the federal government, through the National Institutes of Health, have made massive investments in research and development. For example, the Pharmaceutical Research and Manufacturers of America

(PhRMA) has estimated that the pharmaceutical industry spent $21.1 billion on R&D in 1998. This represents more than twice the amount, $8.4 billion, that private industry invested in pharmaceutical R&D in 1990, and more than ten times the $2 billion spent in 1980. This spending has resulted in full product pipelines that can be expected to bring forth a cornucopia of new products in the next century. According to PhRMA, drug manufacturers are now developing 316 new medicines for cancer; 96 for cardiovascular disease; and 124 for HIV disease, to name a few.

On the horizon, discoveries in genetics also are expected to increase exponentially the number of targets for drug intervention in just a few years. The Human Genome project is a global initiative to map and sequence the whole human genome by the year 2005. According to PhRMA, drug interventions are being actively researched for about 500 health conditions. Once the Human Genome project is completed, scientists anticipate research to increase six to 20 fold to 3,000 to 10,000 conditions. Thus, it seems likely that the drugs now coming to market are the beginning of a vastly expanded and revolutionized medical armory.

Direct-to-Consumer Advertising of Prescription Drugs

Over the past decade, direct-to-consumer (DTC) advertising has revolutionized the marketing of prescription drugs. Traditionally, such advertising was limited to medical journals and trade publications aimed at physicians. Since 1985, when the FDA lifted its moratorium on promotion directed to consumers, this form of advertising has exploded. In 1991, pharmaceutical companies spent $55.3 million to promote prescription products directly to consumers. By 1998, outlays on DTC advertising had multiplied over 20 fold to reach $1.3 billion. Since the FDA relaxed its regulation of broadcast advertising in 1997, TV ads for prescription drugs have proliferated.

Surveys of both consumers and physicians show that DTC ads for prescription drugs are effective in stimulating demand for branded products. The drugs that tend to be advertised are those that are widely used and have a minimum of side effects. In March-April 1997, PREVENTION magazine and the American Pharmaceutical Association (APhA) jointly sponsored a telephone survey of 1,200 consumers nationwide. One of the purposes of this survey was to investigate consumers' response to prescription drug ads. At that time, the survey found that 63 percent of consumers could recall seeing a DTC prescription drug ad. Of this group, almost a third (31 percent) reported that they had asked their doctors about a medication that they had seen advertised. Nearly one in three of these people had asked the doctor for a prescription for the advertised drug. Nearly three-quarters (73 percent) of the time, the physician complied with the request.

Physicians report that an increasing number of their patients are aware of branded prescription drugs and ask for particular products because they have seen them advertised. In 1998, IMS Health surveyed 2,000 doctors nationwide to assess their attitudes toward the expanding use of DTC advertising. Two-thirds of the physicians reported that DTC advertising was the source of brand awareness for their patients, versus 56 percent a year earlier. Over half (53 percent) also reported an increase in the number of patients requesting prescription drugs by brand name, versus 41 percent a year earlier.

Scott-Levin Associates, a Pennsylvania firm that provides consulting services to the pharmaceutical industry, found that physician visits made in connection with heavily advertised drugs rose last year. According to their 1998 Physician Drug and Diagnosis Audit, while overall visits to physicians rose 2 percent between January and September 1998, visits for heavily advertised conditions such as allergies rose 11 percent. For some conditions, the increases were even higher; patient visits for high cholesterol climbed 19 percent.

DTC advertising can promote the public health by encouraging patients with undiagnosed and untreated conditions to see their doctor. However, this consumer demand also contributes to health benefits costs. One Blue Cross and Blue Shield Plan found that five heavily advertised drugs accounted for approximately 10 percent of its prescription drug benefits costs in 1998. Table 1 below shows a comparison of the Plan's drug usage and costs for the first half of 1998 versus the same period a year earlier prior to the advertising campaign. The Plan found that its costs per member for each of these heavily advertised drugs rose from 32 to 90 percent during this period.

TABLE 1.—COMPARISON OF DRUG USAGE AND COSTS FOR A BLUE CROSS BLUE SHIELD PLAN, FIRST SIX MONTHS OF 1998 VERSUS 1997

Drug	Condition	% Change—Number of Prescriptions	% Change—Number of Patients	% Change—Cost per Member
Prilosec	Heartburn	+47%	+41%	+52%
Prevacid	Heartburn	+75%	+72%	+74%
Claritin	Antihistamine	+37%	+30%	+32%
Allegra	Antihistamine	+52%	+45%	+52%
Fosamax	Osteoporosis	+78%	+81%	+90%

Increases in Generic Drug Prices

Generic drugs are the chemical equivalent to brand name drugs but are significantly less expensive. While generic drugs are typically used to lower health care spending, the price of generic drugs has begun to rise as a result of consolidation in the industry. While not having as great an impact as the other trends we have highlighted (demographic trends, the flow of new drugs or DTC advertising), higher generic drug prices are contributors to overall higher prescription drug costs.

In sum, BCBS Plans have experienced a rapid acceleration in prescription drug costs over the past few years. BCBSA expects pharmacy costs to continue to rise, propelled by the medical needs of an aging population, the flow of new technology, and strong consumer demand. As this occurs, health insurers will need to manage prescription drug benefits as effectively as possible in order to keep premiums affordable.

II. STRATEGIES FOR MANAGING DRUG BENEFITS

BCBS Plans use a range of programs to deliver pharmacy benefits and ensure that drugs are used in ways that are both clinically appropriate and cost effective. Some BCBS Plans contract with outside prescription benefit managers (PBMs) to perform claims processing, negotiate volume discounts on their behalf, and oversee the retail distribution of drugs to their members. Others provide these management functions in-house, and a few have created their own PBMs. In any case, some of the most important strategies for managing drug benefits are the following:

Formulary Administration:

Formularies are lists of drugs that health plans cover. Some Blue Cross and Blue Shield Plans maintain "open" formularies, which provide beneficiaries with broad access to all approved medications. However, many health plans are moving to selective formularies, which give certain drugs preferential status. Under selective formularies, drugs that are not on the "preferred" list are covered if the prescribing physician receives "pre-authorization" from the plan. BCBS Plans generally have avoided the use of so-called "closed" formularies, which restrict coverage to drugs on an approved list without exception. BCBS Plans also maintain internal review procedures to consider cases in which a requested drug has been denied to a patient.

Most health plans develop formularies under the guidance of a pharmacy and therapeutics, or P & T, committee. P & T committees are comprised of pharmacists and physicians representing a range of clinical specialties. They evaluate available drugs on their clinical effectiveness, safety, and cost before deciding which drugs will be given preferential status on the plan's formulary. Typically, P & T committees give preferred status to breakthrough drugs or those lacking effective alternatives, and to safe and effective drugs that cost less than other drugs in the same therapeutic class. P & T committees may also develop guidelines for coverage of drugs that are not on the formulary's "preferred" list. Plan administrators use these guidelines when they make "pre-authorization" decisions.

Preferred Provider Arrangements with Retail Pharmacies:

Health plans may also negotiate discounts by contracting with networks of retail pharmacies to become preferred providers in their geographic area. In general, networks will provide higher discounts in exchange for greater exclusivity (i.e., more volume). However, reducing network participation may limit beneficiaries' access to pharmacies. Hence, health plans must make a tradeoff between providing their members with convenient access to retail outlets and reducing costs. Some plans offer mail order pharmacies to obtain volume discounts and provide financial incentives (e.g., eliminating front-end deductibles for prescriptions filled by mail) to encourage their members to use them.

The emergence of Internet pharmacies recently has posed a challenge to preferred provider networks. Most plans have arrangements to reimburse members who purchase drugs outside preferred networks (e.g., in an emergency or when they travel). However, the Internet provides consumers with access to Web sites from which they can obtain prescriptions for popular drugs, such as Viagra (Pfizer's drug to treat impotence), simply by filling out an online questionnaire and paying a fee. The consumer may then visit an online pharmacy to have the prescription filled and be reimbursed by their health plan. The physicians and pharmacies that participate in this online drug distribution system may lack the appropriate credentials and operate beyond the reach of traditional regulatory safeguards. For this reason, health plans face increasing challenges to ensure that their enrolled populations use drugs safely and appropriately.

Beneficiary Cost Sharing:

BCBS and other health plans have recently increased the use of financial incentives to sensitize beneficiaries to the cost of drugs, from which they have historically been insulated. Over the past year, many plans have implemented tiered-copayment structures. Under these structures, plan members share the cost of expensive drugs that have safe and effective, but less costly, alternatives. The intent is to encourage members to use drugs that are both clinically efficacious and cost effective.

Three-tiered structures, which classify drugs into three categories with differing levels of copayment, are now becoming popular. For example, one BCBS Plan recently established the three-part classification shown in Table 2 below. Tier 1, consisting of generic drugs, has the lowest copayment. Tier 2 contains branded drugs that are clinically effective, cost effective, and meet the needs of most patients. These drugs require a moderate copayment. Tier 3 drugs, with the highest copayment, are branded drugs with a generic equivalent or branded therapeutic equivalent in Tier 2. This tier also contains drugs that are rarely used as the first line of treatment of a disease or condition.

TABLE 2.—AN EXAMPLE OF PRESCRIPTION DRUG TIER DEFINITIONS AND COPAYMENTS

Tier 1	Tier 2	Tier 3
All generic drugs	Preferred brand drugs	Non-preferred brand drugs
Lowest copayment	Brand name drugs that are clinically effective, cost-effective and meet the needs of most patients.	Brand name drugs that have a generic equivalent or a therapeutic alternative available in Tier 2
	Second lowest copayment	Brand name drugs not usually used as the first line of treatment
		Highest copayment

Each health plan sets its own copayment structure using one of two approaches. Some plans require a fixed dollar copayment that varies by tier: for example, $10 for Tier 1; $20 for Tier 2; and $30-35 for Tier 3. Other plans prefer to use different percentages of co-insurance for Tiers 1, 2 and 3.

Clearly, tiered cost sharing will be most effective in controlling costs in situations where generic drugs or less expensive branded alternatives exist. However, they will have little impact on the spending associated with breakthrough technology.

While drug benefit costs continue to rise, we hope these cost containment strategies will help to rein in drug costs. Unfortunately, some policymakers, at both the state and federal level, support proposals that would undermine these cost containment tools. For example, some have supported measures that would jeopardize the use of formularies. We urge Congress to reject these types of proposals.

III. MANDATING DRUG COVERAGE IN ALL MEDIGAP PRODUCTS

Congress and the Administration are concerned about the access of senior citizens to needed medication because the traditional fee-for-service Medicare program does not generally provide coverage of outpatient prescription drugs. Today, approximately two-thirds of Medicare beneficiaries obtain such coverage from other sources: Medicare+Choice Plans, Medicaid, employer-sponsored retiree plans, and Medigap.

Medigap offers those who seek protection from Medicare's cost sharing the choice of 10 standardized packages, three of which provide prescription drug coverage. An estimated 15 percent of those enrolled in Medigap plans select one of these three plans. The remaining 85 percent choose one of the other 7 standard plans, which are more affordable because they lack prescription drug coverage. Medigap plans have proved popular in the market place. A July 1998 report from the Department

of Health and Human Services Inspector General found that 88 percent of beneficiaries are satisfied with their Medigap policies.

Some federal policymakers have advocated restructuring Medigap so that all packages include coverage of prescription drugs. The intent behind these proposals is laudable; increasing seniors' access to needed medications. However, a report recently released by BCBSA and the Health Insurance Association of America (HIAA) suggests that these proposals, if enacted into law, would actually reduce seniors' access to Medigap coverage because they would raise average premium costs for beneficiaries by at least $1,000 annually. Such an increase would force many Medicare beneficiaries to drop Medigap, thus leaving them to bear the full cost of Medicare copayments and deductibles. As you consider reforming Medicare, we urge that you keep Medigap affordable and ensure that beneficiaries have a choice of products by not mandating drug coverage for all products.

Because three Medigap plans are now available for seniors who want prescription drug coverage, these proposals would not increase Medicare beneficiaries' access to drug benefits so much as reduce the access of those with lower incomes to any supplemental coverage.

IV. ADDING A DRUG BENEFIT TO MEDICARE

BCBSA shares Congress's concern that Medicare beneficiaries have access to affordable prescription drug coverage. We recognize that since Medicare's inception prescription drugs have assumed an increasingly important role in improving and maintaining the quality of health care. However, we would urge Congress to proceed with caution in developing a Medicare prescription drug benefit, as drug costs are the fastest growing segment of health care.

As my testimony has outlined, private-sector experience suggests that a Medicare drug benefit would be very costly. It will be critical that any Medicare drug proposal include incentives for appropriate drug utilization, as well as programs to manage costs.

A key design element will be whether the new drug benefit is mandatory or voluntary for beneficiaries. The cost of the program will be lower if all Medicare beneficiaries are enrolled in the prescription drug program. However, many beneficiaries now obtain their drug coverage from their previous employers and may pay nominal costs. If the program is mandatory, these individuals may perceive that they are being "forced" to pay for something they already have.

If the new benefit is voluntary for Medicare beneficiaries, we would anticipate that the individuals who are most likely to opt-in are those who have high prescription drug costs. This would make the program more expensive for everyone.

Finally, even with state-of-the-art cost-containment tools, prescription drug costs continue to rise in the private sector. Congress must be willing to confront the challenge of managing costs and ensuring adequate benefit design if it moves toward adding a new Medicare drug benefit.

V. CONCLUSION

Health plans have developed a number of strategies for addressing the rising cost of prescription drugs, although it is still too soon to tell how successful they will be.

As you debate the benefits and costs of adding a prescription drug benefit to Medicare, I would urge you to familiarize yourselves with what the private sector is doing to contain drug costs—the government would need to use these types of strategies for Medicare. As a first step, Congress should not enact legislation that would undermine these cost containment efforts. Congress should also avoid the unintended consequences of proposed Medigap changes by not mandating prescription drug coverage under all standardized options.

Thank you again for the opportunity to testify today.

Prepared Statement of Leighton Read

Mr. Chairman, Members of the Committee, thank you for the opportunity to testify today on the issue of Medicare modernization and the possibility of adding a new drug benefit to the program.

I am Leighton Read, Chairman and CEO of Aviron, a seven-year-old biopharmaceutical company in the San Francisco Bay Area established specifically to create a new generation of vaccines to prevent important diseases in children and adults. Prior to founding this company, I served on the faculty at Harvard Medical School and School of Public Health, where I practiced internal medicine and conducted re-

search on the cost-effectiveness of new medicines. For the past 12 years, I have been involved in organizing and financing several successful biotechnology start-up companies.

This morning I am testifying on behalf of the Biotechnology Industry Organization (BIO), representing over 840 companies, universities, research institutions, state biotechnology associations and affiliates in 46 states.

BIO asked me to testify because I am co-chair of a board level committee focused on health insurance programs including Medicare and because of my experience in developing new vaccines, an area of the pharmaceutical market where the government has played a particularly strong role in purchasing decisions.

There are four points I would like you to consider as you discuss modernizing Medicare and new drug benefits:

1. Smaller biotechnology companies—many of which are years away from having commercial sales—are in the forefront of discovering, developing and bringing to market the next generation of life-saving medicines, a majority of which are targeted at preventing or curing diseases that affect seniors.
2. The visibility of costs associated with today's prescription drugs and biologicals reflects the extent to which such breakthrough products are transforming health care. This highlights the importance of ensuring access for seniors and integrating outpatient medicines into the overall system.
3. Just as we must ensure that seniors have access to the drugs and biologics currently on the market, we must ensure that the stream of innovation remains healthy so that all of us can have access to the products of tomorrow. Medicare reform and coverage policies developed in Washington have a direct and immediate impact on the ability of biotech companies to raise the necessary capital to conduct research and bring these products to market.
4. Increasing seniors' access to prescription drugs through fiscally responsible, decentralized, pluralistic private-market structures is the best way to preserve patient choice, improve quality and encourage innovation. Direct and indirect price controls will drive investment away from biotechnology research.

Small Biotechnology Companies Are Having a Big Impact

Our nation's free-market system led to the development of the most technologically advanced drugs and biologics in the world. Biotechnology is playing a critical role in this advancement. Biotechnology companies are working on the diseases and conditions that disproportionately affect seniors and the disabled. BIO's member companies are developing a wide range of preventive and early detection technologies such as vaccines and genetic screening tests.

Our companies are developing potential cures for debilitating diseases like rheumatoid and osteoarthritis, Alzheimer's and Parkinson's disease. Many are working on improved treatments for the chief causes of death and hospitalization for seniors: cancer, heart disease and stroke.

Although fewer than 5 percent of the 1,274 biotech companies in the United States have products on the market today, the industry expects a great number of FDA approvals in the near future. To date, over 80 biologics and vaccines are on the market. Twenty-one of these were approved in 1998 alone, so the pace of innovation is clearly accelerating. There are over 300 biotech products in the pipeline in phase two or phase three clinical trials. Almost all of these are being developed by U.S.-based companies.

In the past, large drug companies marketed products created largely from their own internal R&D pipelines. Today, a great deal of the translation from basic biomedical research to commercially viable technology is taking place in small companies, such as Aviron. To an increasing extent, large pharmaceutical companies are outsourcing the drug and biotech discovery process, and concentrating on later-stage clinical development and channels of distribution. In biotech companies, teams driven by entrepreneurial spirit and a sense of urgency have greatly accelerated the pace of innovation. To be sure, these smaller companies often need the resources of larger pharmaceutical companies to complete product development and reach global markets. The resulting corporate partnerships offer clear evidence of the value of biotechnology innovation. Those few biotechnology companies that have been able to market their own important new medicines offer even more dramatic testimony.

DRUGS AND BIOLOGICS ARE TRANSFORMING HEALTHCARE

The American success story of pharmaceutical and biotech innovation is the very reason that new prescription drug benefits are under consideration today. Precisely because breakthrough medicines are changing the face of health care, they represent a larger and larger share of the overall enterprise. This is not bad news. It

is good news that we have people out of the hospital, avoiding surgery, and alive because they are taking medicine as outpatients!

Innovation in drugs and biologics will continue to displace other treatments and procedures and open up new options for patients with poor choices today. As our medical systems become more sophisticated, we must find ways to further integrate and coordinate the important components of care. We believe this can best be accomplished in the setting of long-term, sustainable reform of the Medicare program.

THIS DEBATE DRAMATICALLY AFFECTS BIOTECH INNOVATION

BIO members recognize that seniors and the disabled need better access to drugs and biologics. Due to the way in which this industry receives its start-up and subsequent research funding, the policies discussed today will strongly affect our future.

As the power of "the new biology" became apparent, we witnessed an unprecedented flow of billions of dollars of private capital into small biotech companies. More recently, high-tech and Internet companies have diverted the attention of venture capital and growth stock investors. Last year, the biotech industry invested $9.9 billion in research and development to improve and expand treatment options for patients. Few of our companies have revenues, much less profits, so the industry generated a net loss of $5.1 billion the same year. In previous years, this shortfall was largely funded from private sector investment. I have raised $240 million in the form of venture capital, public equity and convertible debt to support Aviron's vaccine programs over the past seven years.

As the products of tomorrow move through the R&D pipeline into larger-scale clinical trials, the need for cash goes up dramatically. Our industry is facing a critical capital shortage that could be exacerbated by the current debate. A recent report by Ernst & Young estimates that 25 percent of biotechnology companies have less than one year of cash remaining; 46 percent have less than 2 years of cash in the bank. Aviron has never had more than three years' cash on hand since its inception.

One reason earlier-stage biotech companies are finding it more difficult to raise capital in today's market is a growing understanding that this technology requires a much longer-term investment compared, for example, with software development. Another problem is that many institutional investors will not buy stock in companies with less than a $1 billion market capitalization. Over 90 percent of our companies have market caps of less than $500 million.

Reform discussions will profoundly affect the ability of small and medium-sized biotech companies to raise the capital they need to complete clinical trials and bring products to the patients who desperately need them. Potential changes in the Medicare program are being scrutinized by already cautious investors as to the likely impact on risk and reward. Hasty decision making now could lead to serious unintended and long-term consequences for biomedical research.

EXPAND ACCESS AND PRESERVE INNOVATION WITH PRIVATE SECTOR SOLUTIONS, NOT PRICE CONTROLS

Because biotechnology companies are so dependent on continued access to private sector investment, the flow of innovative products is quite fragile. Our investors require the promise of an appropriate reward for the long development cycles of biotechnology products. They are exquisitely and immediately sensitive to signals from Washington. Even the threat of price controls or a further concentration of government purchasing power will dry up investment in biotech projects that must frequently be re-funded to move forward. I can tell you from personal experience that it was very much more difficult to raise money for Aviron during the debate on the Clinton health care reform plan and our progress was delayed as a result. Many members of Congress have made it a point to avoid the rhetoric of government price controls. Our industry applauds this vote of confidence in the free market. An over concentration of government purchasing power, however, can be just as destructive. The concern is that a dominant government purchaser will not have an incentive to negotiate a fair price.

This fear of arbitrary confiscation of our ability to gain a fair reward runs deep. I have personally heard senior executives from large pharmaceutical companies say that they would not consider R&D on vaccines for certain diseases because, if successful, "the government would just take it way." Wouldn't it be a big step backwards for society if companies working on cures for breast cancer had to shelve their promising research because the financial reward for investors was diminished? Today's level of biomedical investment is based on today's mix of private sector and government purchasing practices, and the perception of how these may shift in the future. Schemes to "reapportion" the mix between private sector and government

purchase prices will shift investment away from innovative products. In this regard, a proposed extension of government "best prices" to prescriptions for Medicare recipients will be extraordinarily damaging to innovation.

My office is in Mountain View, the heart of Silicon Valley, where it costs hundreds of millions of dollars and takes several years to build a new "wafer fab" to manufacture the next generation of microprocessors. Imagine the reaction of high-tech investors if the federal government were to suddenly commandeer (at its best price) a substantial percentage of the private market for microprocessors! What if those investing in the next generation of automobiles found out that the federal government was planning to set prices for all car purchasers over age 65? It typically takes even more time and money to bring a new biotechnology product all the way through to the market than these other important innovations.

BIO members and our investors know that someone must ultimately weigh the cost, risk and benefits of new technology as part of an informed purchase decision. If we are to avoid the mis-pricing that inevitably occurs with a single dominant purchaser, we must rely on other market mechanisms. Fortunately, there is a new breed of increasingly sophisticated private sector buyers on the scene. The market operates best when beneficiaries have choices among these organizations and their providers. The more decentralized the system, the closer these decisions can be moved to individual patients and their physicians. In such a pluralistic and decentralized structure, competitive forces will lead to the best decisions on how to deploy and price innovative new products.

New benefits must also be fiscally responsible, so as not to threaten the security of future beneficiaries. We believe that the best solution would be in the context of long-term Medicare reform. If interim solutions are necessary, they must focus on those individuals with the greatest financial and medical needs.

CONCLUSION

Mr. Chairman, as you move forward to improve prescription drug access for seniors, we encourage you and your colleagues to keep in mind the vital role that smaller, not-yet-profitable biotechnology play in creating the drugs and biologics of tomorrow. Choose market-based structures as the foundation of any additional Medicare benefit. The unintended consequences of direct or indirect price controls or an over concentration of government purchasing power could delay or prevent development of the medicines that you or I or millions of current and future seniors will rely on.

The biotechnology industry looks forward to working with you to find a solution. Thank you.

Prepared Statement of Jeff Sanders

I am Jeff Sanders and am here representing the Pharmaceutical Care Management Association (PCMA). I am Senior Vice President of PCS Health Systems, one of the two largest pharmacy benefit managers in the United States. I am responsible for product development and management, client analytical support, and pharmacy networks. PCS is a wholly owned subsidiary of Rite Aid Corporation, one of the nation's largest drug store chains. I thank you for the opportunity to present our views and extend, in person, a willingness to help craft an efficient, high quality, and workable Medicare pharmacy benefit program.

EXECUTIVE SUMMARY

The testimony that follows presents an overview of the PBM industry and the services and programs we offer.

We also present a summary of the trends in prescription drug costs payers confront and a summary of prescription drug costs for seniors. These are supported by PCS analyses in two appendices.

We also highlight the PBMs values ensuring quality pharmaceutical care, producing savings in the prescription drug benefit, and making the benefit patient-friendly. The testimony stresses the innovation that occurs regularly within our industry.

We feel it is extremely important that a Medicare prescription drug benefit support the valued services PBMs now provide and allow the type of continuing innovation now occurring for private plans.

INTRODUCTION TO PCMA

The Pharmaceutical Care Management Association (PCMA) represents managed care pharmacy, pharmacy benefits management companies (PBMs), and their part-

ners in pharmaceutical care. PCMA serves its members and America's healthcare system by promoting education, legislation, practice standards, and research that foster high quality, affordable pharmaceutical care. PCMA members serve more than 150 million individuals and employ more than 9,000 pharmacists. To further put our role into perspective, over two-thirds of the 2.8 billion prescriptions dispensed annually are covered by managed healthcare.

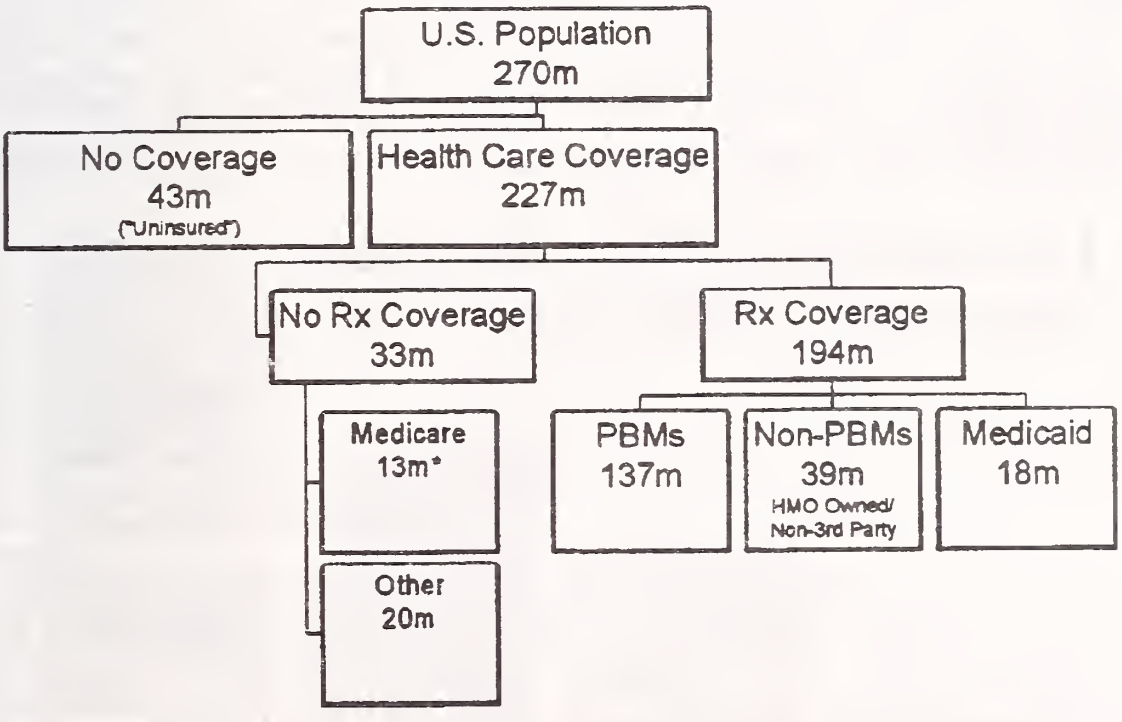
PCMA's mission is to assure quality standards throughout managed care pharmacy, manage escalating healthcare costs for providers and patients, and promote managed pharmaceutical care as a high quality, cost-effective method of prescription medicine delivery.

PCMA has more than 140 members that range widely in size, structure, scope, and variety of the services they provide. PCMA members are leaders in innovation, quality improvement, and the utilization of new technology to deliver and constantly improve pharmaceutical care. Besides dispensing prescription medicines and processing claims, our member organizations provide a number of patient-centered services, such as compliance monitoring, disease management, case management, outcomes assessment, and drug utilization review.

PBM MARKETPLACE

Approximately 227 million Americans have some sort of health insurance coverage. Of these, PCS estimates that approximately 194 million have prescription drug benefits. Of the 33 million individuals who have health coverage but not drug coverage, approximately 13 million are enrolled in Medicare.

Drug management responsibility falls into three distinct categories. PBMs (e.g. PCS, Merck-Medco Managed Care, and Express Scripts) provide benefits for approximately 137 million individuals, which represents 71% of those members with third party pharmacy coverage. Other non-third party processors, including internally managed HMO-based PBMs such as Kaiser Permanente and Aetna provide benefits for approximately 39 million people. The remaining 18 million are covered by various state administered Medicaid plans. (See diagram below.)



INTRODUCTION TO PCS

PCS Health Systems, Inc. manages and monitors 300 million individual prescriptions each year, representing $10 billion in drug expenditures, for 56 million Americans. Included among PCS' customers are about 5 million people under the Federal Employees Health Benefit Program (FEHBP), 10 million HMO/PPO members, 15 million employees of self-insured companies, 143 insurance carriers, many Blue Cross Blue Shield plans, state employees, and union members. These customers are served by PCS through dedicated teams of sales and customer service representatives and are supported by 17 regional sales offices and a clinical operations office in Minneapolis, Minnesota.

HISTORICAL OVERVIEW

In The Beginning—While prescription drug benefits are now common in today's workplace, this has not always been the case. Thirty years ago, most employees could count on medical, surgical, and dental coverage from their group health plans, but prescription drug coverage paled by today's standards. By the late 1960s insurers were being asked to provide prescription drug coverage; however, with this new benefit came a myriad of problems for insurers. Most notably, prescription drug coverage posed a claims administration nightmare for insurance companies who, at that time, were only geared to administer large, well-documented medical or surgical claims.

In order for prescription drug coverage to work on a large scale, it became apparent that a specially developed claims administration system had to be created. This system had to be able to effectively and economically handle the high volume of prescription drug claims that was equal in number to all other forms of health claims.

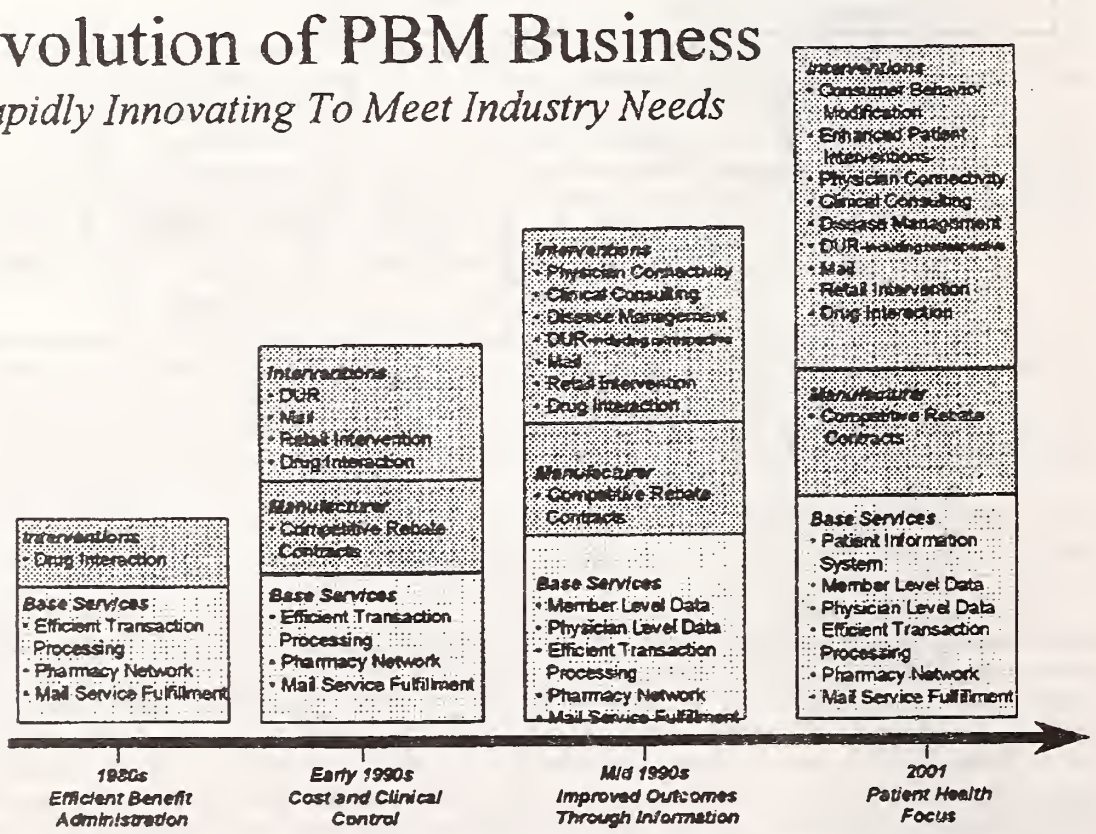
PCS was founded in 1969 with the objective to develop a prescription drugs claims administration system that would satisfy the needs of the payers and patients, provide proper processing of claims, and accomplish this at minimum cost. Out of this effort, Pharmaceutical Card System, Inc. was born. (Our company's name was later changed to PCS Health Systems, Inc.)

1970s: Rapid Growth—Innovation was the key to PCS' and our competitor's rapid growth. Eligible employees received a plastic identification card that could be presented to any of the thousands of pharmacies in the PBM network. The eligible employee paid only a small copayment required by his or her health plan. The pharmacist collected the balance due from the PBM. For the employee and the employer, the card greatly simplified the prescription drug benefit. The PBM industry also pioneered mail service pharmacy benefits, which allowed patients to easily get their medications through the mail at discounted prices.

The 1980s: PBMs Goes Online—PCS, followed by other PBMs, introduced online electronic drug claims processing in 1987. Online processing was welcomed by payers, pharmacists, and patients as the new standard for handling prescription drug claims.

The 1990s: Managed Pharmaceutical Care—During the 1990's, PBMs really became pharmacy care benefit managers, evolving from administrative agents or mail service providers. Services were added that produced savings and improved the quality of care.

The following chart outlines the recent evolution and innovation in our industry:



PBM PRODUCTS AND SERVICES

Today, insurance companies, managed care organizations, employers, and consumers are demanding that PBMs provide programs to both control rising drug costs and deliver clinically appropriate, high-quality health care for patients.

To respond to these market dynamics and address the needs of both payers and patients, PBMs have developed a broad range of services to meet the dual objectives of improving both clinical and economic outcomes.

PBMs adjudicate pharmacy claims, identify pharmaceutical cost outliers, deliver educational and therapeutic-support materials, administer effective disease prevention and management programs, guide patients and physicians to the most appropriate, cost-effective drug options, and track health and economic outcomes.

Most importantly, PBMs are increasingly called upon to tailor combinations of programs and services to meet unique requirements of each market segment and each client. For example, PCS offers four standard formularies, yet manages over 200 different formularies on behalf of its clients. PBMs are called upon to advise customers on which mix of services and programs, plan design, and program features will deliver the best results and meet customers' objectives.

Following is a summary of programs and services that PBMs can offer to help health care providers and payers reduce their drug costs, while ensuring quality for members.

Claims processing and adjudication—Unlike the medical claims processing industry, which continues to be viewed as costly, slow, and prone to data collection errors, PBMs have set the highest standards in the health industry through the use of electronic pharmacy claims adjudication.

For example, PCS alone processes over 300 million claims annually, most in less than two seconds. Each claim adjudicated is run through several hundred clinical and financial edits, ranging from drug-drug, drug-age, and drug-pregnancy edits to eligibility and plan design edits. This electronic system also allows us to offer a discounted drug pricing structure at the point of service. In fact, the efficiency of computerized systems has helped reduce the cost of processing a prescription claim from $6 to less than $1. This dramatic reduction in cost has enabled many employers, both large and small, to be able to provide their employees with a prescription benefit.

Retail Pharmacy Networks—PBMs are expert at contracting with pharmacies to develop pharmacy networks that can meet unique client demands and for balancing beneficiary access with deeper pricing discounts. PCS offers clients choices of pharmacy networks with varying levels of discounts (narrower networks usually having deeper discounts). PCS offers four broad national networks; but, it manages over 365 custom pharmacy networks.

In addition to the standard pharmacy networks and pricing terms, PCS recognizes pharmacies make discretionary decisions that can have an impact on costs and quality. Because of this, PCS has worked aggressively to involve and reward the retail pharmacist for providing services that can help the plan and the member. These services include special "performance networks" which reward pharmacies for meeting goals around such measures as generic dispensing, therapeutic intervention, and most cost-effective bottle size. Pharmacies are measured against peers, regionally and nationally. PCS has developed customized software, distributed to thousands of pharmacies, to aid these pharmacies in measuring and improving their own performance.

PBMs are called to help employers and health plans identify possible cases of prescription drug fraud and abuse, which is an estimated $100 billion annual burden. PCS' fraud and abuse detection program, which utilizes our extensive prescription claims database, identifies not only pharmacists who show patterns of unusual prescription activity, but physicians and plan members as well. Computer analyses are reviewed quarterly, comparing actual activity to performance standards. These reviews trigger on-site pharmacy audits and educational visits to further investigate and resolve the issues.

In support of our network pharmacies, PCS maintains a dedicated pharmacy help desk staffed by a team of specialists who are available to answer questions relating to a member's prescription drug benefit.

Mail Service Pharmacy—Many PBMs provide a mail service pharmacy option to clients. Mail service offers certain clients even higher discounts on drugs and also provides a benefit that is more for certain populations. For example, receiving prescriptions by mail can be especially helpful for seniors on long term maintenance medications. Clinical programs, such as DUR and disease management, are provided with mail service benefits.

Formularies—A formulary is a specific list of drugs that are included with a given plan for a client. Insured members are covered for prescriptions if the drug appears on the formulary list. Formularies have enabled PBMs to successfully achieve price concessions from drug manufacturers, while ensuring clinical program integrity. In that regard, PBMs have developed a variety of formularies to meet the differing needs of our clients. These range from open or voluntary formularies to restricted or closed formularies. PCS offers several "off-the-shelf" formularies or preferred drug list options; yet, because of the unique demands of our client base, we have developed and currently manage approximately 200 client specific formularies.

Rebate Arrangements—PBMs negotiate with manufacturers for rebates on behalf of our clients. Rebates are generally available on branded, single source products. While there are no hard and fast rules, rebate levels are usually related to how effectively the formulary is managed. Manufacturers will pay higher rebates if they believe the volume or market share of their products of their products will increase due to better formulary management. As a result, PBMs offer clients choices of how to manage their formulary, with rebate levels that may vary in some situations. Rebates belong to our clients (employers or insurers), although PBMs often negotiate a portion of the rebates as part of a financial arrangement with the client for managing the pharmacy benefits program.

Generic Dispensing/Alternatives Programs—PBMs offer a number of services to clients, such as Maximum Allowable Cost (MAC) programs. These programs are incorporated into pharmacy network agreements and our claims adjudication processes to encourage increased dispensing and the use of generic alternatives to maximize savings.

Therapeutic Alternatives—Another major driver in the quest for more cost-effective prescribing has been the use of therapeutic alternatives when products are equivalent in efficacy. These programs, used to various degrees in the industry, have helped clients achieve higher utilization of more cost-effective products, and have helped increase rebate levels. PCS currently has over 26 million members participating in its own voluntary therapeutic interchange program.

Drug Utilization Review (DUR)—These programs are run retrospectively, concurrently, or prospectively to help identify potential utilization issues and to correct them at the patient, physician, or pharmacy levels.

Last year, PCS sent over 2.5 million retrospective DUR letters to physicians. PCS also pioneered Quantum Alert(R), the first nationwide, on-line pharmacist messaging and clinical data system. This concurrent DUR program alerts the pharmacist to therapeutic duplications, high drug doses, possible drug interactions, and excessive utilization at the point of service. In 1998, PCS issued more than 61 million concurrent DUR alerts, five (5) million of which concerned potentially dangerous or even life-threatening adverse drug events.

Utilization Management—Drug utilization continues to climb, due to a combination of factors including demographics, changing medical practices, direct-to-consumer advertising, and expensive new therapies. To assist our clients, PBMs have applied a wide range of utilization control measures, including prior authorization, managed drug limitations, managed access for specific patients, and step therapy (e.g., for antibiotics and ulcer medications). These programs are intended to reduce unnecessary drug use, assure drugs are used in proper clinical circumstances, and safeguard the patient. These programs allow for unique combinations that reflect the goals of each client and balance clinical objectives with potential member disruption. For example, the FDA and clinical experts recommend the following:

> Toradol is a non-steroidal anti-inflammatory drug (NSAID) that carries a significant risk of serious adverse effects when used at higher doses or for longer periods than recommended by the manufacturer in the drug's product literature. Specifically, the manufacturer recommends that Toradol be used only for moderately severe acute pain, and that such use be limited to five days of therapy and to a dose not exceeding 40mg (4 tablets) per day.

In PCS' case, we have implemented specific programs that allow our clients to limit the use of Toradol consistent with manufacturer recommendations in order to help ensure the safe use of this drug by our client's members. The criteria used by PCS for the drug limitations and prior authorization programs for Toradol have been developed by PCS' clinical staff and reviewed and approved by an independent medical committee to ensure that the criteria are appropriate and aligned with optimal pharmaceutical care with the drug. This program is specifically designed to help ensure that Toradol, while covered as a benefit by most of PCS' clients' plans, is used safely and effectively.

Disease Management Programs—PBMs, in general, have been successful in developing and implementing disease management programs that focus on achieving improved health outcomes through appropriate drug therapy. They do this by

leveraging extensive retail and mail-based drug claims data and delivering patient-specific education to members, their pharmacists, and their physicians. Typical examples of disease management programs include those for diabetes, cardiovascular disease, and asthma. Clients' clinical issues, members' needs, and internal capabilities often differ. As a result, programs vary widely and PBMs offer customized combinations to suit specific needs.

Support of Physician Decision Making—Current health plan structures often require primary care physicians to make more decisions regarding drug therapy regimens. In turn, PBMs are called on to provide information about these therapies as well as provide an unbiased perspective of the clinical and economic impact of associated prescription decisions. As an example, PCS employs 130 clinical pharmacists to interface directly with physicians, providing them not only with up-to-date information on new and existing drug therapies, but also recommending clinically equivalent, cost effective alternatives for these therapies. Our significant data warehouse capabilities allow us to identify individual physicians with prescribing patterns that merit ongoing consultation, whether by phone, mail, or face-to-face. We can also generate reports for physicians that can help them understand their own patterns and identify the potential savings to payers and beneficiaries associated with prescribing changes. Many PBMs are also working to deliver pharmacy related information to physicians electronically and this approach holds great promise for the future.

Member focus—In order to help members better manage their health, PBMs have developed communications that that help them "navigate" through their benefit plan offerings. Easily understood information is more important now than ever. As examples: PCS offers a suite of member communications which can be customized at the client's request; and, has recently developed a privacy protected web-site for members that allows them to track their prescription history, refill prescriptions, and learn more about their specific condition and appropriate drug therapies.

Member Services—PBMs maintain call centers dedicated to patient concerns. These resource services focus on responding to individual patient calls for help in resolving questions related to the individual's prescription drug benefit.

Client Services—As clients continue to "right size" and outsource benefits administration functions, PBMs have responded by developing sophisticated and comprehensive call centers to accommodate complex questions. These questions can cover a variety of topics, ranging from eligibility to plan drug coverage.

Reporting Capabilities—In addition to paper reports, clients are asking PBMs to provide ways to access or personally manage data related to their health benefits plans. In particular, payers are interested in physician prescribing patterns, drug spend by therapeutic class, total drug spend, and member drug utilization patterns. In response to this need, many PBMs have developed unique software applications that provide clients with on-line analysis tools that can be used to measure and improve their plan's performance. The analysis capabilities can be tailored in consideration of client needs and expertise.

Economic Arrangements—The foundation for our industry's pricing has primarily been fee for service, typically expressed as an administrative fee per claim. PBMs generally guarantee access to pharmacy networks at a set discount off the average wholesale price (AWP) for drugs, plus a dispensing fee for the pharmacy. If formulary management services are involved, the client receives rebates from manufacturers. PBMs often contract for a share of these rebates as a means of administering the client's drug management program. The pricing of services can also vary depending on the needs of the client.

Additional services, such as disease management programs, continue to be provided either on a fee for service basis or in exchange for a share of savings generated for the client.

Capitation is rarely used in the PBM industry for the following reasons:

1. Philosophically, pharmacy costs often offset medical costs; therefore, a capitation on pharmacy costs, alone, tends to create the wrong incentive. Focusing only on drug spend and minimizing these costs does not provide the solution to reducing overall health care expenditures, and may, in fact, increase total medical costs.

2. PBMs rarely control all factors driving drug spend. For example, HMO contracts with physicians can have a significant influence on pharmacy expenditures. Also, many HMOs run internal disease management programs with explicit objectives to increase drug utilization.

Consultative Services—PBMs work with clients to design benefit plan features and approaches that fit their unique needs and marketplace situations. As examples, PBMs can provide expert advice on proper copay and coinsurance structures to achieve customer goals of savings and satisfied beneficiaries.

PCS has developed computer based modeling tools to assist payers with assessing all the financial implications of proposed changes. PCS also consults with plan sponsors on the potential for aligning physician payment and incentives with the pharmacy plan objectives, as well as what information is most valuable to physicians to meet these objectives. In sum, we evaluate each of our clients separately and work with them to deliver the best mix of services, programs, plan design, and features to meet their individual objectives.

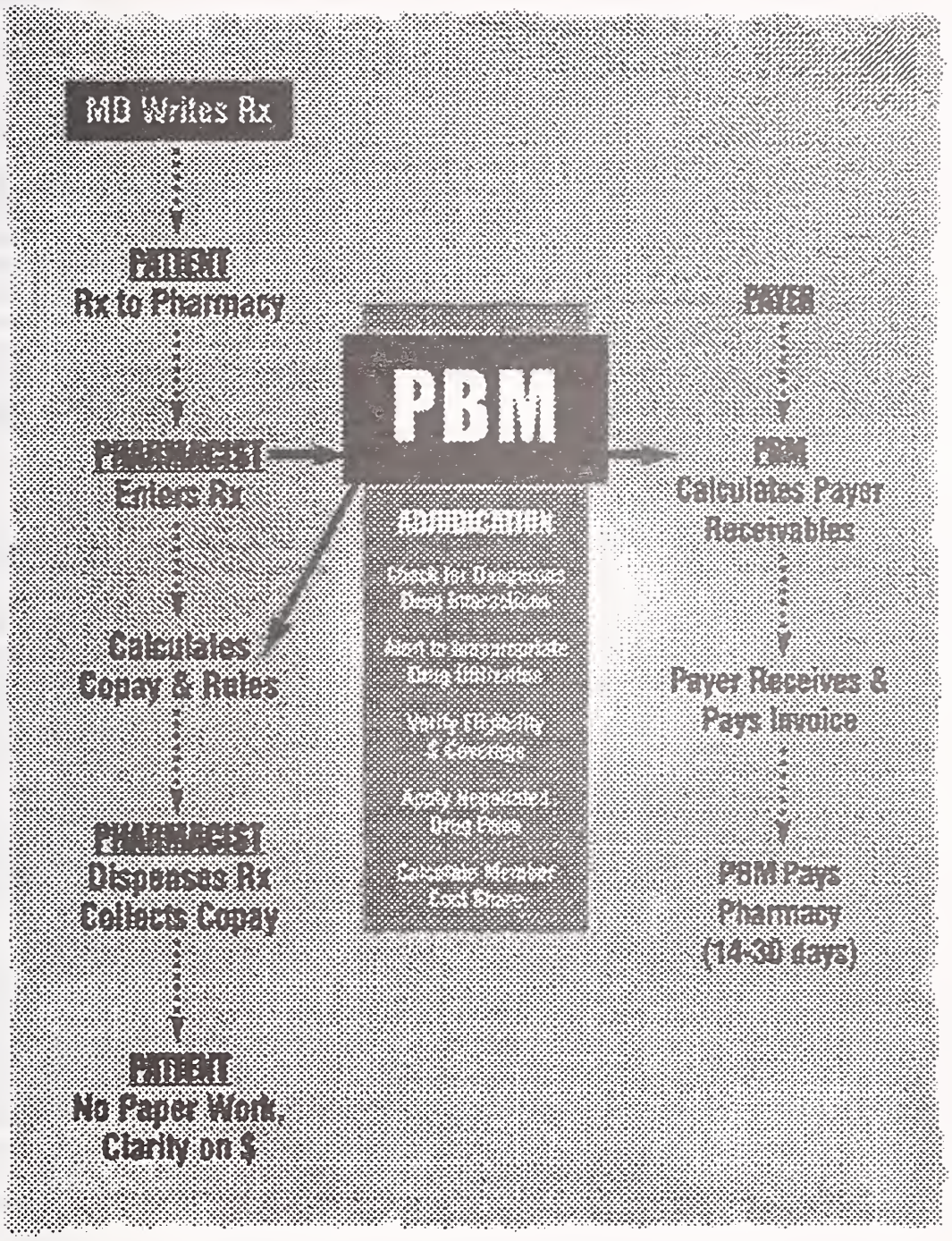
PATIENT PRIVACY

In providing these services to health plans, patients, and physicians, PBMs utilizes the claims data obtained from processing and adjudicating the prescription transactions. At PCS, we stringently protect patient privacy and the confidentiality of this highly sensitive medical information. We take our stewardship of this information very seriously and go to great lengths to ensure that only authorized individuals have access to the data. This includes the patient's physician, the patient's health plan, and those acting on behalf of PCS who have a need to know in order to provide health benefit services under the patient's health plan or to respond to questions from the patient. No other outside entity has access to patient-identifiable information, including PCS' parent company, Rite Aid. Patient-identifiable information is never sold or used for direct-mail marketing purposes. Beyond strictly limiting access to patient information, PCS protects its data through physical security of its computing facility, technological measures that incorporate data encryption and passwords, and a corporate policy that is stringently enforced. We understand that our competing PBMs have similar policies.

SUMMARY

Health providers, payers, and members have all benefited from a history of innovation in the PBM industry. Competition has fostered member, physician, and pharmacy-friendly programs that have helped payers meet their goals of providing a cost-effective prescription drug benefit, without sacrificing patient confidentiality. These solutions have been developed and implemented in a customized way that reflects the continued differences in preferences and objectives of our varied clients.

The following chart illustrates the very basics of the relationship between a PBM and its key constituencies.



DRIVERS IN THE GROWTH OF DRUG COSTS

Retail drug costs in the United States have almost doubled from 1992 to 1998, increasing from $49 billion to $94 billion. It is important to note that these numbers represent drug spend increases for the entire U.S. population, including uninsured and cash paying customers who typically generate a lower rate of drug expenditures relative to the insured population.

Experience shows that trends for benefit plan sponsors are significantly higher, ranging from 14% to 18% from 1997 to 1998. Many plans with rich benefit designs and/or older membership base experienced trend increases up to 40% in 1998.

Typically, about 3 percentage points of this increase are attributable to price increases on current drugs. The remaining drug cost increase is due to two factors: utilization (increasing number of prescriptions per member per year) and intensity (new, more expensive drug therapy and changes in therapy mix). PCS estimates that approximately one third of drug cost increase is due to utilization, i.e., members taking more drugs, and two-thirds is due to the introduction of newer, more expensive drugs that replace older, cheaper drugs for certain treatment regimens.

Also worthy of note is the increase in the percentage of retail prescriptions paid for by third parties. In 1991, 28% of prescriptions were covered by third parties; by

third quarter, 1998, the percentage rose to more than 64%, and has continued to rise.

THE LEADING DRIVERS OF RISING DRUG SPEND CAN BE GROUPED INTO THREE MAJOR CATEGORIES:

1. Environmental Factors

- Aging of the American population and increasing life expectancy
- Shift toward more aggressive medical diagnosis and treatment standards, especially in chronic disease states such as diabetes, high blood pressure and high cholesterol
- Increase in third party coverage of prescription costs, especially flat copay plans, which de-sensitize consumers to the actual costs of drugs

2. New Pharmaceutical Product Development

- Dramatic increases in the number of new brand name drugs coming to market each year
- Increased product development emphasis on drugs to treat chronic conditions
- Increased emphasis on life enhancing and lifestyle drugs

3. Pharmaceutical Manufacturer Marketing Practices.

- Dramatic increases in direct to consumer drug advertising
- Increased focus on direct to physician selling, with drug sales forces increasing 48% from 1995 to 1998

Given that many of the factors driving drug costs will continue through the turn of the century, PCS expects the overall national drug spend to continue to increase for the next few years at growth rates of 14% to 18%. Many drug benefit plan sponsors will face significantly greater growth rates depending upon plan design, health plan demographics, and member cost sharing.

These drivers and their associated impact on overall costs are discussed in detail in the attached Appendix A.

PCS OVER-65 ANALYSIS

As people age, they use more drugs. PCS has conducted analyses of its over-65 population to better understand how America's seniors utilize drugs. On average, patients over 65 fill approximately 20 prescriptions per year as compared to about six prescriptions for individuals between the ages of 20 and 30 years.

Analysis of specific therapeutic classes reveals significant differences in the types of drugs used. Antibiotics, H2-Antagonists (gastric treatment), and oral diabetic agents rank as the top three drug classes in the under 65 population. In contrast, cholesterol-reducing agents (HMGs), hypertension medications (Calcium Channel Blockers), and ulcer medications (PPIs) are the top three drug classes consumed by the over 65 population. Cardiovascular drugs represent 36% of drug use by seniors.

Among people over 65, there are wide differences in drug costs. PCS conducted a cluster analysis of its over-65 members and found that this member population can be categorized into three groups: Low Cost, Middle-of-the-Road, and High Cost.

When viewed from a total cost perspective, the "80/20" rule of thumb does not apply:

- The Low Cost segment accounts for 68% of the population but only 27% of the total costs
- The Middle-of-the-Road segment represents only 27% of the population, yet accounts for 44% of the total costs.
- The High Cost group, which represents about 5% of the population, accounts for 16% of the total costs.

Worthy of note is the observation that gender and age have less of an impact on drug costs than the disease state. In particular, patients with diabetes tend to generate significantly higher drug costs than others, especially when the diabetes coexists with other conditions such as cardiovascular disease and depression. A detailed discussion of these issues, along with the quantitative findings of PCS' analysis of the senior market is found in the attached Appendix B.

PHARMACY BENEFIT MANAGEMENT VALUE

PBMs work to ensure the quality of drug care to produce savings in the pharmaceutical benefit and to make the benefit patient-friendly. And, PBMs work with clients to help them design benefits and tailor programs to meet specific needs.

IPBMs ensure the quality of pharmaceutical care—For successful PBMs, clinical considerations and quality of care come first and quality of care features underlie all of our programs. PBMs offer drug-drug interaction and other drug safety alerts

on line. This enables the dispensing pharmacist to identify and resolve issues before the patient obtains the prescription. PCS alone sent alerts on 5 million potentially dangerous drug interactions in 1998. PBMs also have varied programs that support physicians in their efforts to provide quality care. PCS sends letters to physicians that outline current prescribing standards and protocols, and offer the physicians unbiased cost and efficacy information. As noted earlier, we sent over 2.5 million letters to physicians in 1998 alone. We support this with face-to-face visits to physicians by clinical pharmacists.

PBMs also provide ad hoc quality efforts. For example, even prior to press reports on Viagra's dangerous interaction with drugs containing nitrates, PCS studied its database so that we could alert physicians to the danger. Carefully complying with privacy concerns, we made the information actionable by identifying, for the prescribing physicians, any of their patients on both Viagra and nitrates. While responses varied across the industry, this approach is part of what PBMs offer. We believe there are many cases where services such as these have saved lives, prevented hospitalizations, and improved lives.

PBMs produce savings—In 1997, The General Accounting Office (GAO/HEHS 97-47 FEHBP Pharmacy Benefits) studied the savings PBMs produce for the Federal Employee Health Benefits Plan (FEHBP). GAO studied three FEHBP plans and found savings in 1995 ranged from 20%-27% relative to what would have been spent without the PBMs. Savings resulted from pharmacy and mail service discounts, manufacturer discounts negotiated on the FEHBP plans' behalf, generic and brand interchange programs, prior approval programs, drug utilization review, disease management, and coordination of benefits. The mix of savings and programs adopted by the three FEHBP plans varied. As important as the savings, GAO also found extremely high federal employee satisfaction with the program, with 93% to 98% of respondents noting satisfaction with their benefits.

GAO analyzed the 1995 FEHBP program. A similar study done on the 1999 program would find additional services and services in place, and savings being even greater for the FEHBP plans. The study would also find considerably higher drug spend for the FEHBP plans in 1999 than 1995, as the overall trends in drug spending have affected all third party payers. This has created an onus on PCS and the other PBMs that serve these plans to produce yet more savings in coming years.

As was the case with the GAO study, many of our clients look at savings and patient satisfaction within the pharmacy benefit. Increasingly, however, our industry looks at the pharmacy benefit's value to the overall medical care of the patient. Study after study has documented the consequences of poor patient compliance with their therapy, patient misuse of drugs, prescribing, errors, and drug interactions because different physicians unknowingly prescribed drugs that chemically interact with each other. Studies regularly show that up to 25% of all elderly hospital admissions result from something going wrong with drug therapy, much of this being preventable. One study (Johnson and Bootman, 1995) documented $76 billion in annual drug related morbidity and mortality costs in the US ambulatory setting. As noted above, today's PBMs actively play a role in improving pharmaceutical care; and, in fact, statistics would be much worse without our current programs.

New technologies allow PBMs to increase our linkage to overall health care and medical costs, which can provide us with the potential to put a much greater dent in the $76 billion in unnecessary costs. And, with pharmaceutical innovation continually providing new or different ways to treat conditions, the need for management of patient drug therapy is increasing dramatically.

PBMs make the benefit patient-friendly—Surveys consistently show that pharmacy benefits rank high in what members like most about their overall health care plan Not only does pharmacy rank high in relative terms, but also in absolute terms. As part of the previously described study on PBMs in the FEHBP program, GAO found patient satisfaction with their pharmacy benefit ranged from 93% to 98%.

High satisfaction results from services such as on-line adjudication of pharmacy claims which permits patients to know their total financial responsibility when picking up their prescription. If there is a problem with coverage or some other benefit nuance, they are able to know at the point of dispensing, not weeks or months after. There is no paperwork to submit. This is a standard of service that has become so ingrained and universal that no one thinks about the dramatic contrast with how medical bills are often paid.

The Internet has opened a new channel to greatly expand the communication that PBMs provide to enrollees. With this capacity, we can, with appropriate privacy protection, provide patients with more information about the drugs they are taking, how to take them, the effect of drugs on their medical conditions, and improve the ease of using mail service pharmacy. We see this as a significant opportunity to pro-

vide patients with a better understanding of their pharmacy benefit and a means to involve them in managing the pharmacy benefit for their own good.

PBM value is high; so, too, are remaining needs—PBMs offer much value, but there are many issues in managing the pharmacy benefit that still need improvement and solutions. With more new pharmaceutical compounds reaching the market today than at any time in our history, and more of these compounds representing "breakthroughs," the challenges in managing a pharmacy benefit are changing more rapidly than ever. There are many new opportunities (and some old ones) to reduce unnecessary drug use; to improve compliance and how patients take their drugs; and to assure that drug therapies regularly deliver their potential medical benefits.

Just as in medical care, pharmacy practice patterns differ across the country with varying degrees of effectiveness and cost. And, PBMs have further to go in understanding and addressing these variations. The Internet and other technological advances give PBMs and our payer customers a much better opportunity to provide patients, pharmacists, and physicians easier, more timely information so that care options will be better understood and better decisions made.

Finally, as noted earlier, the opportunities to more fully integrate the management of the pharmacy benefit with overall medical care is great.

DYNAMIC CHANGE IN THE PHARMACY BENEFITS MANAGEMENT INDUSTRY

The Pharmaceutical Care Management Association (PCMA) is proud that PBM contributions have led to an accessible, easy to use pharmacy benefit for most Americans. We are proud of the savings we produce—20%-27% for the Federal Employees program—that make these benefits more affordable than they would be otherwise. We are proud of the innovations such as real time, concurrent drug utilization review that has improved the quality and safety of medical care. We are proud that the benefit is efficient and easy to use. We look forward to the many challenges and opportunities that are here now or coming.

Our industry regularly brings innovations and new capabilities to the marketplace that leverage technology, information and relationships with patients and health providers. Competition is fierce in this industry and valued innovations have become necessary to win business. These innovations will provide greater savings, add clinical value, and allow us to accomplish these goals in ways that feel less intrusive to patients and physicians than many of today's medical and pharmacy interventions.

IMPLICATIONS FOR A MEDICARE DRUG BENEFIT

Medicare and its beneficiaries should benefit from today's PBM programs, such as on-line adjudication; formulary management and manufacturer rebates; retail and mail service pharmacy network discounts; generic substitution and therapeutic alternatives; drug utilization review; utilization management techniques such as prior authorization, managed drug limits, and step therapy; a variety of beneficiary education programs; and disease management.

We also feel it is extremely important that a Medicare pharmacy benefit allow the type of continuing innovation now occurring for private plans. We simply cannot freeze our industry as it exists today through a regulatory structure in which it becomes nearly impossible to improve how we deliver the benefit and offer new value-added services. Medicare and its beneficiaries should be allowed to benefit from the new programs and capabilities.

The health care environment is characterized by diversity in the patient and provider sectors. Consequently, multiple approaches to the opportunities and challenges of managing pharmacy benefits have been developed. When confronted with managing pharmaceutical over-use, under-use, or misuse, different PBMs take different approaches. Within PCS, we often pursue more than one approach so that we can more completely address an issue in consideration of the diversity of health delivery across the country. Medicare should allow variation so that approaches can be compared, with the best approaches surviving. This method of evaluation is the very source of much of the improvement that occurs today within PBMs, and across our entire industry.

To us, this means an administrative structure that sets some broad, minimum benefit requirements and beneficiary protections. PBMs should be allowed to compete (PBMs alone or PBM/plans) and innovate, within these broad parameters.

We believe the value of pharmacy information linked to medical information is high, although privacy protection must be in place. In designing the program, pharmacy information should be available to the end medical payer, and specific medical information should be available to the PBM to help it manage the pharmacy benefit. The specifics of this may be intertwined with the overall structure of Medicare, but

technology allows such information exchange to be relatively straightforward—regardless of Medicare's structure. And, of course, we must take care, particularly where a Medicare risk plan is involved, that the PBM stay linked with the managed care plan (likely by contract, as today), so that patient management techniques are integrated between the PBM and the HMO.

Whatever its precise parameters, a Medicare drug benefit should be structured so as to allow the competitive process to operate freely. There is no mechanism better than the marketplace for filtering out the less effective and more costly approaches, and no more impartial or accurate a judge of what works and brings value to the beneficiaries. It is the discipline imposed by the market for PBM services that has brought about the tremendous savings, administrative efficiencies, and clinical advances evident in the delivery of pharmacy benefits today.

Great care must be taken to preserve not simply the current best programs in place, but the market mechanism that is responsible for constantly re-evaluating and improving upon those programs. This will require a discipline of another sort by the government, namely, to avoid micromanaging program details and encumbering benefit providers with rules regarding every aspect of their activities. While these actions may be taken with the best interests of beneficiaries in mind, they serve only to stifle innovation, reward inflexibility, and build bureaucracies. Worse, by undermining the very process upon which the government would be depending to bring about cost savings and clinical improvements, such actions would protect the inefficient and entrench the unresponsive—the very players that an efficient market system would root out first.

Beneficiaries' interests can best be protected and advanced by the government setting minimum benefit standards, outlining broad principles of participation, providing opportunities for program variations and innovations, and establishing an oversight mechanism. Allowed to operate freely, competition will take care of the rest—providing all the incentives to improve performance, and all the penalties for failure. This is how it works today—although imperfectly—in the pharmacy benefit provided in the Medicare risk program and in the FEHBP program.

We understand several approaches are being considered to provide Medicare patients drug benefit coverage and we think several of them are workable. Both the Pharmaceutical Care Management Association and PCS stand prepared to assist in helping achieve the objectives we have outlined above through our expertise.

Thank you for the opportunity to present these views.

PCSHealthSystems℠

June 1999

Drug Cost Trends in the healthcare environment

Implications for Health Plans

PCS Health Systems, Inc.

Appendix A

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Introduction

As the nation's leading pharmaceutical benefit manager, PCS Health Systems is aware of the economic and social impacts created by rising pharmaceutical costs. The purpose of this report is to review the key drivers of drug spend and examine alternative strategies for intelligent drug management. This report will:

- Review 1998 market trend data and examine major drug spend drivers;
- Highlight important therapeutic drug classes to watch in the next few years;
- Forecast 1999 drug spend trends; and,
- Review alternative strategies for intelligent drug management.

Market Trends

Overview

In the United States retail drug costs have almost doubled from 1992 to 1998, increasing from $49 billion to $94 billion (Chart A). This represents an overall drug spend increase of 11.9 percent from 1997 to 1998[1]. PCS expects continued double-digit drug spend increases for the next few years. It is important to note that these trends represent drug spend increases for the entire U.S. population, including uninsured and cash paying customers who typically generate a lower rate of drug expenditures relative to the insured population. Experience shows that trends for benefit plan sponsors are significantly higher, ranging from 14 to 18 percent from 1997 to 1998. The figure also excludes mail order prescriptions, which are growing faster than retail prescriptions. Member demographics, new blockbuster products, and limited consumer cost sharing combine to increase the demand for drugs while allowing for price insensitivity by members. Hence, plan sponsor costs continue to drive upward.

Many plans with rich benefit designs and older members experienced trend increases of 30-40 percent in 1998; this translates to approximately 2.5 to 3 times the national trend rates. Typically, only 3 to 5 percent of this increase is attributable to price increases on current drugs. The remaining increase of 25 to 35 percent is due to two factors: utilization (increasing number of prescriptions per member per year) and intensity (new, more expensive drug therapy and changes in therapy mix). PCS estimates that approximately one-third of this increase is due to utilization, i.e., members taking more drugs; the other two-thirds is due to the introduction of newer, more expensive drugs that replace older, cheaper drugs for certain treatment regimens.

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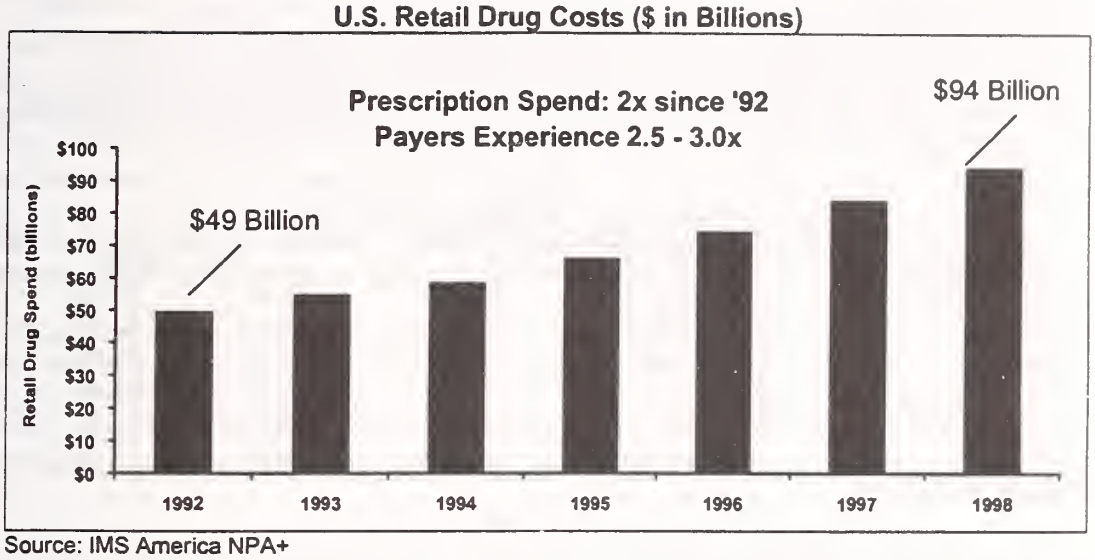
Chart A
U.S. Retail Drug Costs ($ in Billions)



Source: IMS America NPA+

The growth in drug spend has not been restricted to one or two therapeutic classes. Significant cost increases occurred in almost every major disease category (Chart B). For example, from 1997 to 1998, total U.S. retail spend for diabetes increased 42 percent, high cholesterol 32 percent, ulcer therapy 46 percent and mental illnesses 23 percent, and again this understates what most plan sponsors experienced in 1998.

Chart B
Top 10 Therapeutic Classes ($ in Billions)

Drug Class	Treatment Area	1997 U.S. Retail Spend	1998 U.S. Retail Spend	Percent Increase (97-98)
Selective Serotonin Reuptake Inhibitors (SSRIs)	Depression	4.48	5.52	23.2%
HMG Co-A Reductase Inhibitors	High Cholesterol	3.59	4.73	31.8%
Proton Pump Inhibitors	Ulcers	2.76	4.03	46.1%
Calcium Channel Blockers	High Blood Pressure	3.91	4.02	2.8%
Ace Inhibitors	High Blood Pressure	2.89	3.20	10.6%
Anti-arthritics	Arthritis	2.57	2.62	2.1%
H2 Antagonists	Ulcers	2.85	2.51	(12.1%)
Oral Hypoglycemics	Diabetes	1.68	2.39	42.0%
Antihistamines	Allergies	1.48	2.00	34.9%
Cephalosporins	Infections	1.98	1.87	(5.6%)

Source: IMS Health NPA+

Unfortunately, we do not expect this trend of rising drug budgets to reverse in the near future,

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primarily because there is a price to pay for innovation. We now have more effective therapies in many therapeutic classes, however the price of these more efficacious therapies is also often high (Table C). For example Prilosec, used for ulcers is priced at a premium of $3.59 per day of therapy compared to its predecessor cimetidine, now generic and only $0.38 per pill. More importantly, this phenomenon is not only occurring in new therapeutic classes but even the older classes which have been in the market for a while, such as high cholesterol and depression.

Table C
The Price of Innovation (Price per day of therapy)

Therapeutic Class	Predecessor		New Therapy	
Gastrointesintal	cimetidine	$0.80	Prilosec	$3.59
Depression	amitriptyline	$0.17	Prozac	$2.36
Diabetes	glucophage	$0.95	Rezulin	$2.98
High Cholesterol	gemfibrizol	$1.04	Lipitor	$1.80
Chronic Pain	NSAIDs	$1.20	Celebrex	$2.42
Allergy	chlorpheniramine	$0.96	Claritin	$1.23

Source: IMS America

Major drivers of drug costs

Although price does play a role in the increasing drug budget, it is not the only driver of pharmaceutical spend increases. Several broad factors are leading to increased pharmaceutical use, particularly:

1. Environmental Factors,
2. New Pharmaceutical Product Development, and
3. Pharmaceutical Manufacturer Marketing Practices.

Environmental Factors

Several environmental factors continue to play a role in the rising use of prescription drugs. One major reason for increasing drug spend is the *aging of the American population and increased life expectancy*. People over 65 will grow to 20 percent of the population (from 13 percent) by 2030.[2] Drug use rises dramatically as people grow older and develop age-related illnesses. For example, patients over age 65 fill between 9 and 30 prescriptions per year, compared with 2 to 3 prescriptions for patients 25-44[3]. Coupled with increasing life expectancy, an aging population will drive the utilization of pharmaceuticals

Another important factor relates to the *shift toward more aggressive diagnosis and more preventive treatment standards.* As medical research continues to explore how to optimize overall patient care, new clinical protocols evolve. For example, the American Diabetes Association recently lowered the blood glucose level thresholds for diabetes. In effect, this added 2 million individuals to those who meet the guidelines to be treated for diabetes. Similarly, studies have suggested that there may be clinical benefit from starting individuals on cholesterol lowering drugs if their total cholesterol level is greater than 200 mg/dL. This is down from the currently accepted standard of 240 mg/dL. If this newer recommendation is adopted, the number of Americans eligible for cholesterol-lowering therapy will increase from 38 million

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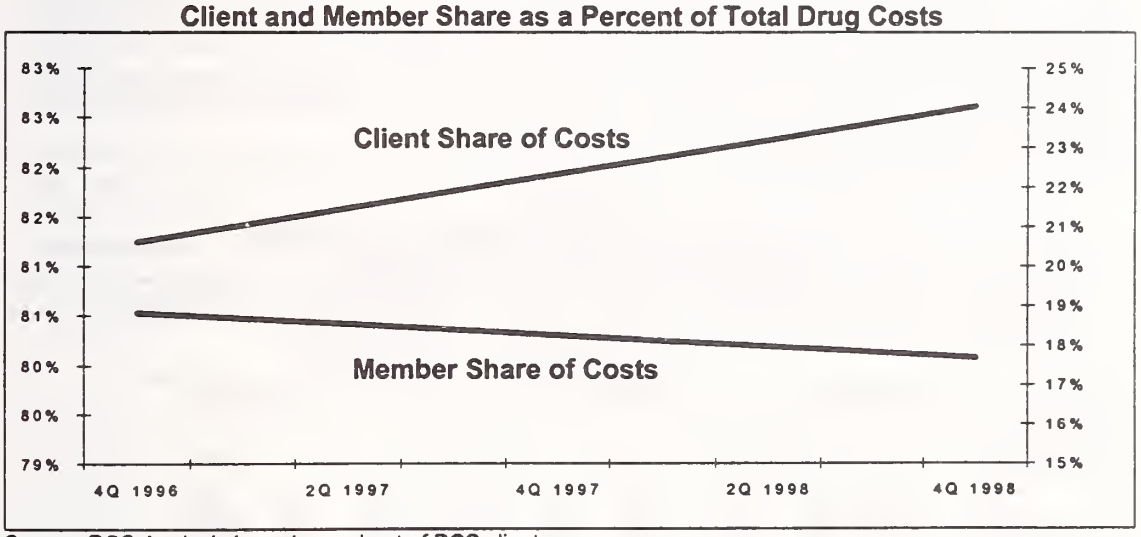
to 97 million.

Finally, the *emergence of consumerism in the health care industry* escalates tension between consumer expectations and financial responsibility. Members are demanding more choices and more flexibility in their benefit coverage. And, with the explosion of healthcare and pharmacy-related internet sites targeted at consumers, accessing health information is becoming easier. More information enables consumers to play a greater role in their own health care decisions. In addition, several legislative initiatives are expected to impact healthcare and pharmacy benefits. Legislation addressing patient rights and privacy, health plan liability and increasing health and pharmacy benefit requirements is expected at either the state or federal level during the next year.

At the same time, minimal economic barriers exist to control the use of drugs. From 1980 to 1986, consumer out-of-pocket responsibility dropped from 66 percent to 34 percent of total payments.[4] PCS' analysis shows the continuance of this trend: since fourth quarter 1996, the *members' portion of total drug cost fell* from 19 percent to 17 percent, whereas *the plan sponsors portion increased* from 81 percent to 83 percent (Chart D).

Chart D
Client and Member Share as a Percent of Total Drug Costs



Source: PCS Analysis based on subset of PCS clients

The shift from cash payment to third party reimbursement indicates widespread acceptance of managed pharmacy benefits among U.S. insurers and consumers. Virtually all of this increase in third party reimbursement has been in flat copayment plans, where individuals pay a predictable low fee per prescription. This places an increasing rate of economic responsibility on the health plan.

Pharmaceutical Manufacturer Marketing Practices

Over the past several years, *pharmaceutical manufacturers have renewed their commitment to field sales forces*. As Table E demonstrates, manufacturers have invested significantly in sales force expansion. From 1995 to 1998, manufacturer sales forces increased 48% to over 57,000 sales representatives in the United States[5]. These field forces target the nation's highest prescribing physicians and concentrate on encouraging the prescribing of the newest—and

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usually more expensive—drugs.

Table E
Pharmaceutical Manufacturer Sales Force Expansion

Company	Total U.S. Reps	New Reps	New Drugs
Bristol-Myers Squibb	4,800	2,100	Pravachol
Merck	4,503	1,675	Singulair
Pfizer	4,437	800	Zyrtec, Viagra
Glaxo Wellcome	3,500	750	Raxar
Others	40,316		
Total U.S. Reps	57,556		

Source: Wall Street Journal and Soloman Smith Barney Equity Research

The other important expansion in manufacturer marketing efforts is *the dramatic increase in direct-to-consumer (DTC) advertising.* Much of the increase in spending can be attributed to the 1997 change in FDA regulations, which makes it easier for manufacturers to place more effective advertisements on television. Manufacturers spent $1.3 billion on DTC advertising in 1998.[6] Pharmaceutical companies are continuing their DTC investment as evidenced by the rise of promotional expenditures (Table F).

Table F
Total Expenditure of Selected Prescription Medicines Advertised to Consumers (All Media)

Brand	Treatment Area	Total Spend Jan-June 97 ($ in Millions)	Total Spend Jan-June 98 ($ in Millions)	% change
Claritin	Allergies	30.2	57.8	91.1%
Pravachol	High Cholesterol	29.9	55.9	86.4%
Allegra	Allergies	31.7	30.8	(2.8%)
Prilosec	Ulcers	16.2	28.0	73.0%
Valtrex	Herpes	8.8	18.5	108.4%

Source: MedAd News October 1998

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New Pharmaceutical Product Development

Advances in the pharmaceutical industry have resulted in dramatically *accelerated product development and increased efficacy of new drugs.* The recent enhancements in the FDA product approval process (e.g., electronic submission, more resources, fast tracking), has doubled new product approvals in the 1990s. Advances in genomics, combinatorial chemistry, high throughput screening, and structure-based drug design are producing new drug development candidates more than 40 percent faster and at 50 percent less cost than just ten years ago. PCS expects more dramatic breakthroughs from current technologies in the coming years.

Not only are more products entering the market, but also product sales volume itself is growing ("the big are getting bigger"). The total number of drugs over a billion dollars in worldwide sales has doubled in three years, from 13 products in 1994 to 27 products in 1997 (Table G).

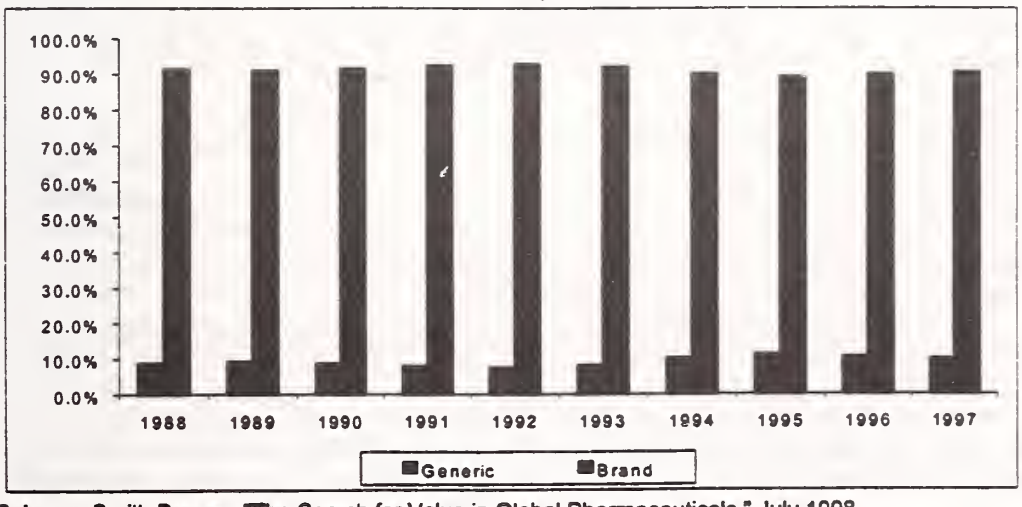
Table G
Drugs over $1 Billion in Worldwide Sales

Sales Volume	1994	1995	1996	1997
Greater than $1.0 billion	8	11	19	17
Greater than $1.5 billion	4	4	2	6
Greater than $2.5 billion	1	2	3	4
Total	13	17	24	27

Source: MedAd News, 1995-1998

In the past, savings generated by generic availability of brand products helped to offset expensive new treatments. However, the rate of new product development is outweighing the potential savings in patent expirations. As demonstrated by the product portfolio of the top U.S. Pharmaceutical Companies, only one of eight companies expect to lose more than 10 percent of total 1997 sales to generic erosion. On the other hand, new products (defined as products introduced between 1997 and 2002) will account for 41 percent of total sales by 2002.[7]

Chart H
Total U.S. Pharmaceutical Expenditures – Generic vs. Brand



Salomon Smith Barney, "The Search for Value in Global Pharmaceuticals," July 1998

Industry Watch: Key Products and Therapeutic Classes

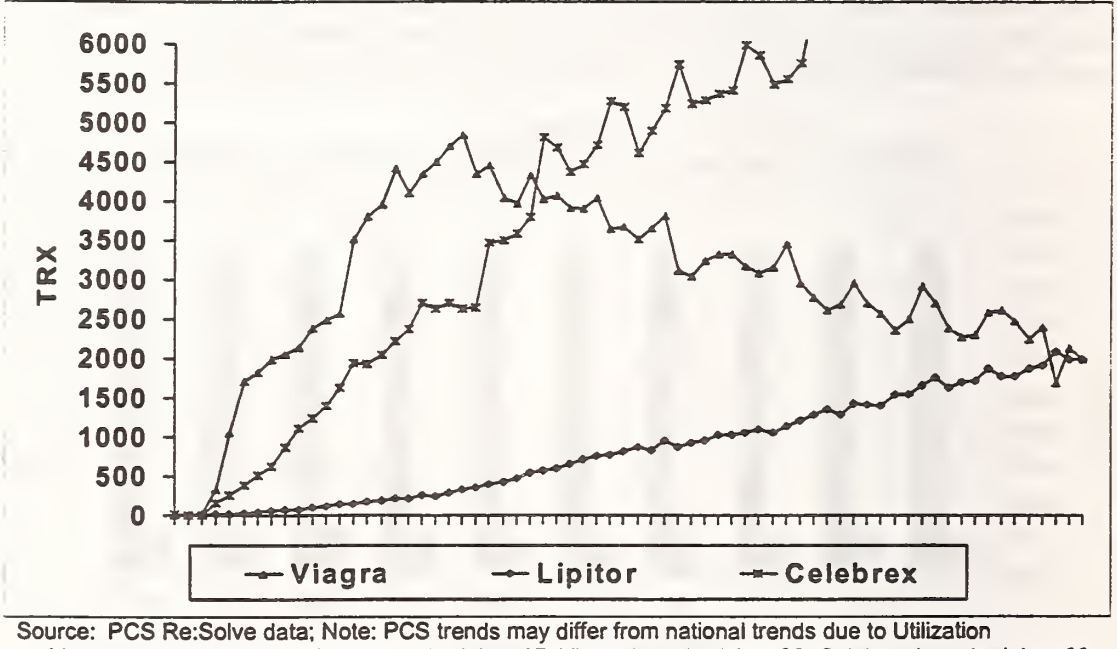
The previous section discussed the long term, sustainable factors driving increases in drug spend. This section highlights specific drugs and drug classes that are creating much of the rising pharmaceutical costs and identifies key classes to watch in the future. Several therapeutic classes deserve particular attention in the next one to two years. These classes are summarized below.

Chronic Pain

Arthritis/Chronic Pain is one therapeutic class in which PCS expects to see significant growth over the next few years. Current therapy for chronic pain is typically Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which include the generic drugs ibuprofen and naproxen as well as the brand products DayPro, Relafen and Lodine. A negative side-effect of NSAID use is that the drugs can cause severe stomach problems with chronic users.

A new class of painkillers, the Cox-2 inhibitors is currently being launched for the treatment of chronic pain. These new drugs lessen the chance of stomach problems due to their ability to selectively target the enzymes that create pain and inflammation. The FDA granted marketing approval to the first new drug in this class, Celebrex in December 1998 for the treatment of osteo and rheumatoid arthritis. To date, Celebrex has become the second largest drug launch in history (Chart I). The second Cox-2 Inhibitor, Vioxx, is expected to be available in pharmacies by June 1999. The impact to plan sponsors budgets may be significant if patients switch from a generic NSAID (which can cost pennies a day) to the new Cox-2 Inhibitors (which cost over $2.40 per day of therapy).

Chart I
Celebrex Launch - Total U.S. Prescriptions by Week



Source: PCS Re:Solve data; Note: PCS trends may differ from national trends due to Utilization Management Programs; Lipitor launched Jan. 97, Viagra launched Apr. 98, Celebrex launched Jan. 99

Diabetes

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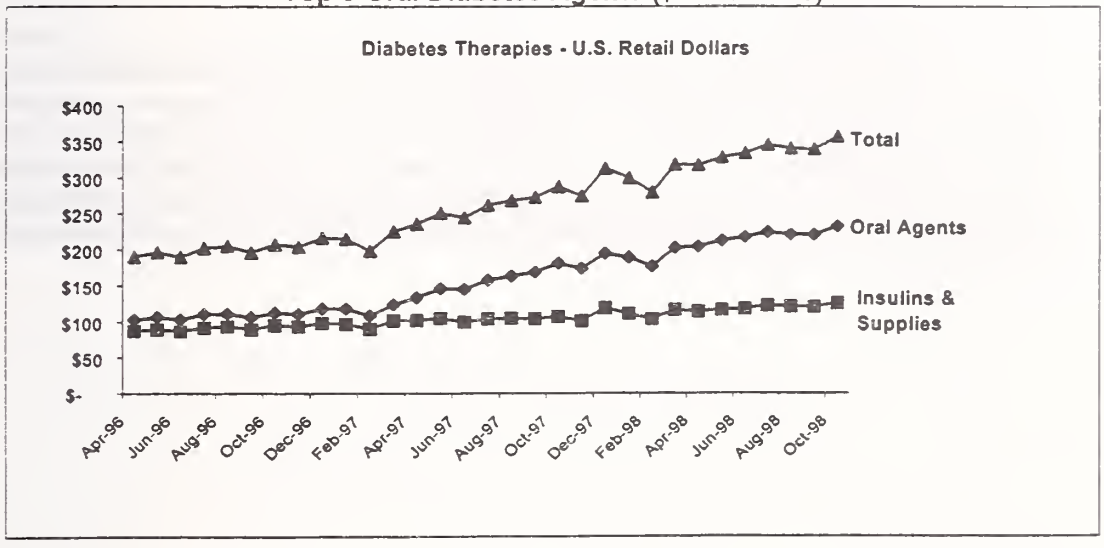
The treatment of Diabetes is another therapeutic class in which PCS expects to see growing drug spend over the next several years. There are two main drivers in this class: new diagnosis standards and new products.

The American Diabetes Association recently lowered the blood glucose level treatment threshold from 140 mg/dl to 126 mg/dl. In effect, this added 2 million people who could potentially receive treatment for diabetes, including both monitoring and drug therapy.

In addition, several new products were recently introduced (e.g., Rezulin, Glucophage, Prandin) and are receiving high acceptance. Patients with even mild diabetes begin with these expensive new drugs. In addition, two new oral products (Avandia, Actos) are expected to available during 1999. These drugs are similar to Rezulin, but are potentially more efficacious. These "second-generation Rezulins" are expected to receive marketing approval in April 1999 and become available by May/June 1999. Also, nearly 18 states have recently enacted legislation mandating coverage of diabetes education, medications and supplies, which will also effect drug spend in this class.

Chart J
Top 5 Oral Diabetes Agents ($ in Millions)



Hypertension

Another therapeutic class to watch is Hypertension. A new class of medication called Angiotensin Receptor Blockers (ARBs) is influencing the utilization of drugs for the treatment of high blood pressure. These ARBs are similar to ACE Inhibitors in their efficacy; however they have a better side effect profile in that they do not produce a dry cough (a common ACE Inhibitor side effect). Compared to other drugs in this class, ARBs are more expensive than the ACE Inhibitors, but cheaper than the Calcium Channel Blockers (CCBs).The ARB class has been expanding significantly over the past several years. The first drugs in the class were launched in the middle of 1995, followed by several in 1997 and early 1998.

Table K
Angiotensin Receptor Blocker (ARBs) ($ in Millions)

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Drug	Approval Date	1998 Sales ($ in Millions)
Cozaar	June 95	$288.2
Hyzaar	June 95	$139.2
Diovan	Feb. 97	$13.2
Avapro	Sept. 97	$63.9
Atacand	June 98	$1.3
Micardis	Jan 99	Launched Jan. 99
Teveten	Dec. 97	Not yet launched

Trend Forecasts

Given that many of the factors driving drug costs will continue through the turn of the century, we expect that drug spend will continue to increase for the next few years at growth rates of 14 to 18 percent. This estimate is comprised of the following components: unit cost inflation at 2 to 3 percent, utilization at 5 to 7 percent (number of prescriptions per member per year), and intensity at 7 to 8 percent (new drug therapy and changes in therapy mix). Depending upon member demographics, member cost sharing, and level of clinical management, drug spend increases of 20 percent or more will be increasingly common.

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There are several key therapeutic classes in which we expect to see very strong growth (over 25%) in the next year. Table L highlights the trends expected in key therapeutic classes:

Table L
Therapeutic Class Trends

Therapeutic Class	% of Spend	Projected Growth
Cardiovascular		
Hypertension	15%	Moderate
ACE Inhibitors	4%	Mild
ARBs	<1%	Very Strong
CCBs	5%	Flat
Hyperlipidemia	8%	Very Strong
Anti-Infectives	9%	Moderate
Gastrointestinal	8%	Moderate
Depression	7%	Strong
Respiratory (Asthma)	5%	Strong
Chronic Pain	4%	Strong
Diabetes	4%	Strong
Allergy	3%	Very Strong
Women's Health	3%	Moderate
Cancer	2%	Moderate
AIDS Therapies	1%	Very Strong
Migraine	<1%	Very Strong
Sexual Dysfunction	<1%	Moderate

Mild: 2-4%; Moderate: 5-14%; Strong 15-24%; Very Strong: Over 25%

Evolution of Drug Management Needs

From 1985 to 1995, the first generation of drug management paralleled overall managed care development. Most efforts focused on price breaks, volume discounts with pharmacies and manufacturers, and the diversion of drug dispensing to mail order. During this same period, drug benefits increased as most health plans converted to low copay drug plans. Major new challenges are emerging that require new approaches to drug benefits. Managing appropriate drug use in today's pharmaceutical environment requires not only a strong foundation of drug and medical information, but also an operations and information technology platform that includes:

- clinical framework based on best practice treatment standards
- plan designs that encourage members to make cost effective choices
- accurate, timely education and information for physicians
- appropriate incentives and risk-sharing relationships with patients, physicians, pharmacies and manufacturers
- technological and systems capability that can deploy interventions rationally while being efficient at the local, operational level
- selective relationships with pharmaceutical manufacturers whose products represent the most cost-effective, medically appropriate therapies
- ability to educate and motivate appropriate plan members and patients about drug selection and utilization
- ability to continually reevaluate best practices based on new medical research and outcomes information.

Specifically, two major challenges will create an urgent need for new strategies:

1. the need to predict, measure, and optimize the scope of drug coverage and cost sharing alternatives in the face of new, more discretionary drug products and unlimited consumer demand.

2. the need to design and successfully administer patient, population and disease-specific programs that manage, over long periods of time, chronic drug use consistent with "best practice" protocols.

This infrastructure or "utilization management system" will involve building new capabilities for drug management. It will resemble or be closely coordinated with the case management and demand management capabilities currently in place to manage medical costs.

Both of these strategies have significant implications for consumers and physicians. Consumers will be asked to pay more for certain drug choices. Managing member expectations of health plan and employer coverage will represent a major challenge, especially at a time when health plans are under increasing public and regulatory pressure to expand services and coverage.

Physicians will be expected to increase the use of treatment protocols in their prescribing decisions. Today, physicians obtain most of their information about drugs from pharmaceutical

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representatives. Once prescribed, new needs for patient monitoring will emerge, either by the physician or, most likely, through new patient management programs.

Conclusions

Meeting the drug spend management needs of the future requires an increasing level of teamwork among all players in the health care continuum. Not only must health plans, providers, patients, and PBMs renew their commitment toward the sharing of medical and pharmaceutical information, but they also must work toward greater standardization of treatment protocols, coverage decisions, and intervention rationales. As pharmaceuticals play an ever-increasing role in overall medical care, the management of their appropriate use will only grow in importance.

Endnotes

[1] IMS Health, Press Release, based on NPA Audit-dispensed prescription data.

[2] U.S. Census Bureau, 1998

[3] Wall Street Journal, November 16, 1998, "Drug Dependency: U.S. Has Developed an Expensive Habit; Now, How to Pay for it?"

[4] Goldman Sachs, "Healthcare: Managed Care, U.S. Research," April 9, 1998, quoting from HCFA, office of the Actuary.

[5] IMS Health September 15, 1998 Press Release

[6] *Journal of Managed Care Pharmacy*, February 1998, "The Patient as a Partner in Prescribing: Direct-to-Consumer Advertising"; originally cited from Competitive Media Reporting, 1996.

[7] Salomon Smith Barney, "The Search for Value in Global Pharmaceuticals," July 1998.

PCSHealthSystems℠

Patterns and Trends in Over-65 Pharmaceutical Consumption

Appendix B

Patterns and Trends in Over-65 Pharmaceutical Consumption

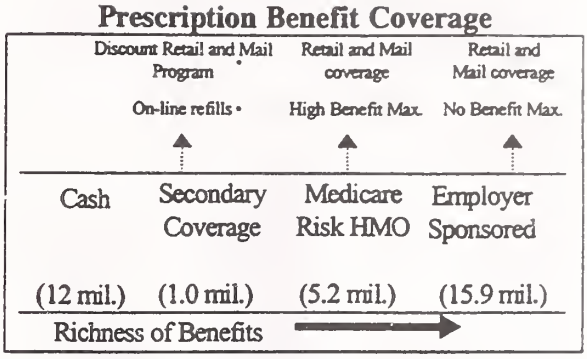
As the nation's leading Pharmaceutical Benefit Manager, PCS Health Systems captures pharmaceutical utilization data for over 56 million Americans, or approximately 20 percent of the U.S. population. In an effort to help understand the unique pharmaceutical utilization patterns of elderly Americans, PCS conducted a comprehensive study of the consumption patterns of its over-65 members. This paper summarizes the findings of this analysis, and includes data in the following categories:

- Distribution of pharmaceutical coverage
- Pharmaceutical utilization statistics
- Demographic patterns in pharmaceutical consumption.

DISTRIBUTION OF PHARMACEUTICAL COVERAGE

Of the 34.1 million Americans over 65 in the United States, PCS estimates that over 65 percent have some level of pharmaceutical coverage, either through primary healthcare coverage or from a secondary source (Figure 1). HCFA reports that nearly 62 percent of individuals who with prescription coverage are covered through primary drug coverage such as a Medicare Risk HMO or an employer-sponsored plan. The remaining 3 percent receive coverage through a secondary source, such as the American Association of Retired Persons (AARP) or other third-party insurance.

Figure 1
Prescription Benefit Coverage



The level of prescription benefit coverage available for persons age 65 and older varies from minimal coverage (e.g., discounts from AARPs Member Choice prescription drug program) to extensive coverage through employer-sponsored health plans. And, although Medicare Risk HMOs have traditionally offered prescription benefit coverage to members, many of these plans are now limiting the richness of their benefit packages.

Medicare Risk Coverage

According to HCFA, Medicare Risk enrollment grew from 441,000 enrollees in 1995 to over 5 million in 1997. According to the 1998 Novartis Pharmacy Benefits Report, approximately 90% of Medicare risk plans currently offer a prescription benefit (Figure 2).

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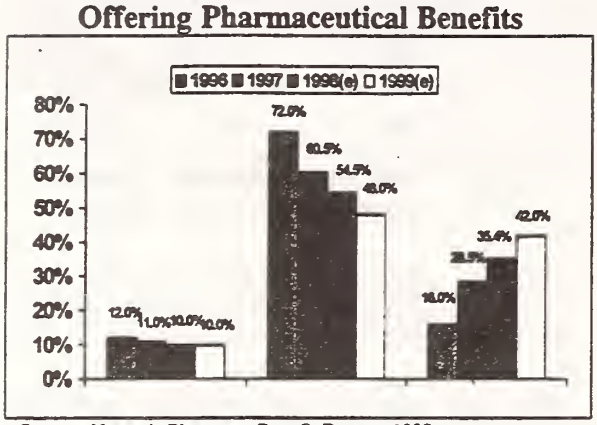
Figure 2
Percentage of Medicare Risk Plans Offering Pharmaceutical Benefits



Source: Novartis Pharmacy Benefit Report, 1998

While benefit designs among the Medicare Risk plans range widely in order balance care management initiatives and budgetary constraints, most plans agree that they will increase controls over the next several years in order to have a higher level of control of their pharmacy costs. Benefit Managers concerned with rising drug costs will continue to implement greater controls in order to try to control rising drug spend.

Results of the Novartis survey show that benefit managers predict increases in the following areas: Prior Authorization, Therapeutic Interchange, and Variable Copayment. Figures comparing 1996 to 1999 note that *Prior Authorization is* expected to increase from 82% to 91%. *Therapeutic Interchange* programs from 32% to 61%, and *Variable Copayments* from 52% to 86%.

In general, Medicare Risk members are charged higher prescription copayments than commercial plan members (Figure 3). Over the next two years, copayment levels are predicted to increase. Benefit plan sponsors who have encountered difficulties in managing pharmacy costs for elderly and chronically ill patients primarily drive this increase. In addition, Medicare Risk members are often willing to pay higher premiums because under traditional Medicare coverage, prescriptions are not covered at all.

Figure 3
HMO Average Copays

	Brand Rxs	Generic Rxs
Commercial/Group	$9.96	$5.53
Commercial/Group Mail Service*	$15.84	$9.42
Medicare Risk	$11.00	$7.25
Medicare Risk Mail Service*	$18.64	$13.21

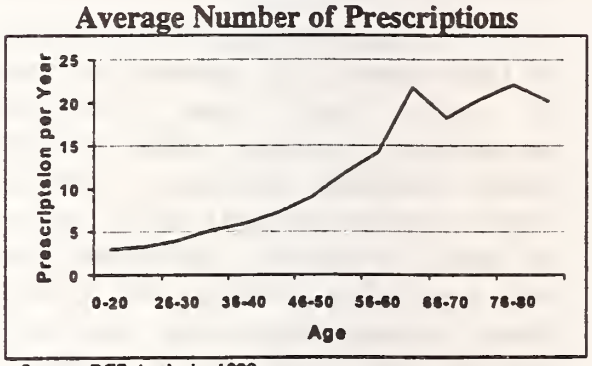
*Typically reflects copay for 3 months of drug

Source: Novartis Pharmacy Benefit Report, 1998

PHARMACEUTICAL UTILIZATION STATISTICS

Prescriptions utilization (the number of prescriptions filled per person per year) increases dramatically with a person's age. The average over-65 year old fills approximately 20 prescriptions per year, compared to approximately six for a person in his or her twenties.

Figure 4
Average Number of Prescriptions



Source: PCS Analysis, 1999

In addition, analysis of specific therapeutic classes reveals significant differences. Antibiotics (cephalosporins), H2-Antagonists and oral diabetic agents rank as the top three drug classes in the under 65 population (Figure 5). In contrast, cholesterol-reducing agents (HMGs), Hypertension medications (Calcium Channel Blockers) and Proton Pump

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Inhibitors (PPIs) are the top three drug classes consumed by the over 65 population (Figure 6).

Figure 5
Top 10 Therapeutic Classes
All Ages

	ICP ($ millions)	% of Total ICP
Cephalosporins	203	2.2%
H2 Antagonists	222	2.5%
Oral Diabetes	281	3.1%
Antiarthritics	298	3.3%
Antihistamines	310	3.4%
ACE Inhibitors	313	3.5%
Calcium Channel Blockers	448	4.9%
Proton Pump Inhibitors	544	6.0%
HMG Co-A Reductase Inhil	697	7.7%
SSRIs	698	7.7%
Total Top 10	4,014	44.3%

Figure 6
Top 10 Therapeutic Classes
Over 65 Population

	ICP ($ millions)	% of Total ICP
HMG Co-A Reductase Inhibit	276	7.5%
Calcium Channel Blockers	210	5.7%
Proton Pump Inhibitors	157	4.3%
ACE Inhibitors	132	3.6%
Oral Diabetes	103	2.8%
SSRIs	90	2.4%
Antiarthritics	87	2.4%
H2 Antagonists	75	2.0%
Antineoplastics	73	2.0%
Other Antihypertensive Agent	65	1.8%
Total Top 10	1,268	34.4%

IMPACT OF BENEFIT DESIGN ON UTILIZATION

PCS provides coverage for over-65 members under a variety of benefit designs. Figure 7 illustrates how overall costs vary considerably depending upon the richness of plan design

The first cohort of members consists of seniors with an exceptionally rich benefit design. These members pay no deductible and negligible coinsurance, and they face no benefit maximums. The annual benefit costs for these seniors ranges from $961 to $1,143 per year.

The second group consists of members with mixed benefit designs, including an assortment of front end deductibles, copays and benefit maximums. Costs for these individuals range from $366 to $622 per year.

Figure 7
Annual Per Person Drug Cost
by Benefit Type and Age

Member Age	Rich Benefits	Average Benefits
65 to 69	$961	$595
70 to 74	$1,116	$622
75 to 79	$1,143	$618
80 to 84	$1,095	$559
85 +	$970	$366

Source: PCS Analysis, 1999

Figure 8 presents the average number of prescriptions filled per member per year for the same two cohort groups. Seniors with rich benefits fill between 18.4 and 26.3 prescriptions per year, while seniors with average benefits fill between 12.6 and 17.2 prescriptions per year.

Figure 8
Annual Number of Prescriptions Filled
by Benefit Type and Age

Member Age	Rich Benefits	Average Benefits
65 to 69	18.4	15.4
70 to 74	21.9	16.3
75 to 79	24.1	17.2
80 to 84	25.5	16.8
85 +	26.3	12.6

Source: PCS Analysis, 1999

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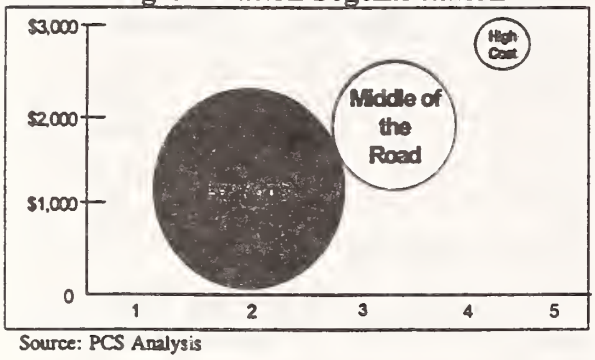
DEMOGRAPHIC PATTERNS IN PHARMACEUTICAL CONSUMPTION

As a means of evaluating prescription consumption differences in patterns among those over age 65, PCS conducted a cluster analysis of its over-65 members. Results indicate that the over-65 population can be categorized into three groups: Low Cost, Middle-of-the-Road and High Cost utilizers.

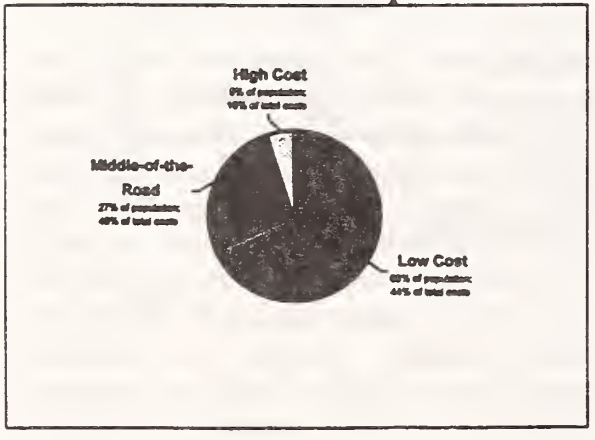
Figure 9
Drug Utilization Segementation



Source: PCS Analysis

The Low cost group accounts for 68 percent of the over 65 population, the Middle-of-the-Road group makes up 27 percent of the population, and the High Cost segment is 5 percent of the total population (Figure 10).

Figure 10
Percent of Over-65 Population



When viewed from a total cost perspective, the "80/20" rule of thumb does not apply. For example, the Middle-of-the-Road segment represents only 27 percent of the population, yet accounts for 44 percent of the total costs. The High Cost group (5 percent of the population) accounts for 16 percent of the total costs. The following section will describe each group in detail.

Low Cost

The low cost group consists of approximately 68 percent of the over 65 population yet this group accounts for only 40 percent of total pharmaceutical costs. The average age of this group is 80.9, and consists of 63 percent female and 37 percent male. On average, the low cost group uses two different types of drugs per year, costing approximately $620.00.

Figure 11
Top 5 Therapeutic Classes
Low Cost Segment

Therapeutic Class	Avg. Cost per Year
Gastrointestinal	$68.37
High Cholesterol	$36.66
Hypertension	$32.56
Chronic Pain	$28.97
Cardiovascular	$22.85

The most commonly used therapies among the Low Cost group are gastrointestinal drugs (i.e., Proton Pump Inhibitors and H2-Antagonists for Ulcers, GI troubles), followed by High Cholesterol medications and therapies to control hypertension (i.e., ACE Inhibitors, Calcium Channel Blockers, ARBs).

Middle-of-the-Road

The Middle-of-the-Road group makes up 27 percent of the over 65 population, and

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accounts for 44 percent of the total costs. This group is slightly younger than the low cost group with the average age being 79.4. The gender mix is fairly consistent with 61 percent female and 39 percent male. The middle-of-the road group uses an average of 3.35 different types of drugs per year with an average cost of $1,845, significantly higher than the low cost group.

Figure 12
Top 5 Therapeutic Classes
Middle of the Road Segment

Therapeutic Class	Avg. Cost per Year
Hypertension	$284.14
Gastrointestinal	$207.61
High Cholesterol	$192.86
Chronic Pain	$101.03
Cardiovascular	$89.22

The most commonly used therapy among the Middle-of-the-Road individuals is hypertension medication, followed by the Gastrointestinal therapies (i.e., PPIs, and H2-Antagonists). Cholesterol-lowering therapies ranked third among the Middle-of-the-Road group.

High Cost

The high cost group consists of only 5 percent of the total over 65 population, but accounts for 16 percent of total costs. On average, this group is younger than the other two groups, with the average age of 78.8.

This group, however, has more health problems than the other two over-65 groups. They use an average of 4.31 different types of therapies per year at an average cost of $3,137, over five times the amount of the low cost group.

Figure 13
Top 5 Therapeutic Classes
High Cost Segment

Therapeutic Class	Avg. Cost per Year
Gastrointestinal	$660.57
High Cholesterol	$298.27
Hypertension	$274.87
Diabetes	$220.61
Depression	$189.64

Like the Low Cost group, the top 3 therapeutic classes for the High Cost individuals are hypertension medications, gastrointesintal therapies and cholesterol-lowering drugs. The difference however is in the average cost per year for the products. For example, the average cost for the Low Cost group for GI therapies is $68.00, while the average cost for the High cost group is nearly ten times that amount at $660.00.

The other driving difference between the High Cost group and the other over-65 individuals is that individuals in the High Cost group are more likely to have Diabetes and Depression than individuals in the other groups. Both of these disease states have expensive drug therapies which are driving the drug spend among individuals in this group.

This cluster analysis, together with PCS' analysis of benefit design and overall drug utilization, clearly demonstrate that there are significant differences in how seniors utilize pharmaceuticals. Understanding these differences can help payers plan and implement pharmacy benefit designs that optimize the clinical value of the drug benefit while maximizing the value of the benefit dollar.

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PREPARED STATEMENT OF HON. OLYMPIA J. SNOWE

Thank you, Mr. Chairman. I appreciate the opportunity to discuss the work I have been doing with Senator Wyden over the past few months on a proposal we call the Seniors Prescription Insurance Coverage Equity Act of 1999, or "SPICE." We think this legislation will be a credible, straightforward approach to mending a gaping hole in our nation's health care safety net by providing Medicare-eligible beneficiaries with access to prescription drug coverage.

At the outset, I want to acknowledge the leadership of Chairman Roth and Senator Moynihan and the Finance Committee for its commitment to finding ways to improve Medicare and to ensure the solvency of the Medicare Trust Fund. I fully understand the critical need to enact legislation that credibly reforms this crucial program.

The lack of coverage for prescription drugs is an issue our elderly face daily and we need to take action—whether or not there is a Medicare reform package. Here we are, at the dawn of the 21st century, enjoying the longest peacetime expansion in our nation's history. The economy's booming. Breakthroughs in science and medicine are a daily occurrence, and when it comes to the latest Dow-Jones) record, it seems like the sky's the limit.

And yet, with all our wealth, with all our advancements, every day in America there are seniors making a choice that no one should have to make. It is the choice between filling the cupboard, or filling a prescription.

We cannot continue to tell the nearly 40 million Americans on Medicare that, when it comes to your medication, they are on their own. What sense does it make to pay for a visit to the doctor, only to have that doctor write a prescription that they can't afford to fill?

But, all too often, that's exactly what happens. Why? When Medicare was designed in 1965, it was modeled after our nation's private health insurance system—a system that relied on inpatient hospitalization and seldom on outpatient preventive services or patient drug therapies. In 1965 we created a hospital-based health care system that works pretty well—if you're hospitalized. But these days, we have drugs for diseases that hadn't even been discovered then. So why should seniors be left behind just because Medicare hasn't caught up?

The Health Care Financing Administration reports that 65 percent of Medicare beneficiaries already have some form of prescription drug coverage. But what they don't report is that it is a band-aid system at best—11 percent of beneficiaries get coverage from Medicaid, 7 percent from participating in a Medicare HMO, 8 percent from private Medigap insurance and 28 percent from employee retirement packages.

All 50 states have Medicaid plans that cover drugs—50 different plans. And in 1997, eleven of them imposed caps on the number of prescriptions that can be covered in a month. It seems that the message to seniors is, don't get sick all at once. And, as you all know, Medicaid is only for the very low income and beneficiaries may have to spend a great deal out of pocket for their drugs—what we commonly refer to as spending down—before they are eligible in a given year for coverage.

When it comes to Medigap, only three of the ten existing plans offer drug coverage, and two of them require a $250 deductible before covering 50 percent of the cost of the drug, and then only up to $1,250. The third plan has a cap of $3,000 with a premium ranging anywhere from $1,699 to $3,171—a burden simply to heavy to bear for all too many seniors.

And when you take into account the fact that drug expenditures have increased by 12.6 percent annually between 1994 and 1997—a rate of growth almost four times that of hospital expenditures, where does all this leave America's seniors? How many elderly across the country make the decision one woman at a senior's meal site that I recently visited in Maine does—to take only two of the three pills her doctor prescribed—because they last longer that way.

Our plan, the Seniors Prescription Insurance Coverage Equity Act, or SPICE, would help that woman in Maine and millions like her across the country—regardless of whether or not Congress tackles Medicare reform this year. It is an effective and comprehensive approach that doesn't add layers of new bureaucracy, doesn't rely on a government-run program, and doesn't in any way jeopardize existing Medicare benefits—or for that matter, the solvency of the program itself.

Senator Wyden and I started laying the groundwork for this approach back in the Budget Committee with a plan to pay for our idea—without resorting to gimmicks or fiscal slight-of-hand. The amendment I offered in the Budget markup allows us to use non-Social Security surpluses for a prescription drug benefit—if this Committee reports out a Medicare reform bill. That amendment passed by an overwhelming bipartisan vote of 21 to 1. In fact, Senators Nickles, Gramm, and Conrad voted for my amendment as members of the Budget Committee.

During floor consideration of the Budget Resolution, Senator Wyden and I offered an amendment that would have expanded the source of available funding to include any new tobacco tax revenue. While we didn't get enough votes to overcome a budgetary point-of-order, we did get 54 votes—enough to put a majority of the Senate on record in support of our approach. In fact, 11 members of the Finance Committee supported the Snowe-Wyden amendment.

In the weeks that followed, Senator Wyden and I have worked to lay down some basic principles for SPICE. Our proposal establishes private, supplemental prescription drug policies offered through a successor to Medigap that will provide seniors with a choice of coverage. If you're enrolled in Medicare, you're automatically qualified, and the federal government will help pay your premiums to an extent determined by your income.

It should go without saying that individuals should be allowed to choose the supplemental drug coverage plan that best suits their needs. I've often found that, if you want to find a good solution to a problem, it's worth taking a look at what Members of Congress have seen fit to provide themselves over the years. And that's exactly what we did in this case. As participants in the Federal Employees Health Benefit Program, or FEHBP, we have freedom of choice—and if it's good enough for us it should be good enough for the rest America's seniors.

Under the Snowe-Wyden plan, similar to FEHBP, seniors would select from a variety of offerings from private insurance companies, and the federal government would subsidize the premium depending on income. This approach is not only better for the consumer, but it keeps costs down by encouraging competition among plans.

We minimize bureaucracy but maximize oversight by creating a single, independent board—called the SPICE Board—that would set forth benchmark criteria for the plans and monitor implementation. HCFA would play no role in the oversight of SPICE.

And most importantly, we provide the greatest help to those who need it most. For those with incomes under 150 percent of the poverty level—$12,075 for a single person and $16,275 for a couple—the federal government would subsidize the beneficiary's entire premium. From there, the percentage is phased-down to a minimum of 25 percent for those at 175 percent of the poverty level—$14,088 for a single person and $18,988 for a couple—and above. Individuals will remain responsible for any co-pays or deductibles.

We believe there is no better or more appropriate way to pay for all this than to use President Clinton's budget proposal to increase the tobacco tax by 55 cents and accelerate the existing 15 cent-per-pack increase.

A Columbia University study published in 1995 reported that smoking-related illnesses cost the Medicare program $25.5 billion in 1995 alone—that's 14 percent of its total expenditures. Assuming this rate holds true, and there's no reason to assume otherwise—tobacco-related health care expenses will cost the Medicare program $486 billion over the next ten years!

I don't pretend that SPICE will address every prescription drug coverage problem for every senior. But there is no doubt it will help millions who currently cannot afford coverage.

We think that this approach stands apart from the rest by providing choice, maintaining a basic level of benefits for all Medicare enrollees, keeping government out of the business of prescription health care plans, and paying for it with logical, reliable, and real funding mechanisms. Our proposal shows that the lack of Medicare prescription drug coverage can be effectively addressed this year, and we hope it will serve as the catalyst for change that is long overdue. This is a solid proposal and I look forward to working with the Committee on this important issue. Thank you.

COMMUNICATIONS

STATEMENT OF THE AMERICAN DIETETIC ASSOCIATION

The American Dietetic Association (ADA) appreciates the opportunity to submit testimony to the Finance Committee as it considers prescription drug benefits for Medicare. The ADA is the world's largest organization of food and nutrition professionals with 70,000 members who serve the public through the promotion of optimal nutrition, health and well-being. Over 80 percent of all registered dietitians work in health care delivery, including hospitals and HMOs, long-term care facilities, and clinics and physicians' offices.

As Congress investigates the potential for providing prescription drug benefits to Medicare participants, it is critical to recognize the positive impact that medical nutrition therapy can have as an integral component in managing disease conditions to lessen or eliminate the need for drug therapies. Medical nutrition therapy involves the assessment of patient nutritional status followed by appropriate therapy, ranging from diet modification to the administration of specialized therapies.

Medical nutrition therapy has been incorporated into the treatment protocols of some of the most common disease conditions that afflict the Medicare population. Controlling diabetes, high blood pressure and elevated cholesterol often requires the use of expensive drug treatments. Studies indicate that medical nutrition therapy provided by nutrition professionals, such as registered dietitians, can be used to help individuals successfully manage their disease conditions through dietary lifestyle changes. As a result, the need for drug treatments can often be substantially reduced or eliminated. Reducing the need for intensive drug therapy may also result in reduced cost and fewer side effects for the patient. This could improve adherence to the overall treatment program.

Clearly, the Congress faces a difficult task in balancing the needs of the Medicare population with the tremendous costs associated with providing a prescription drug benefit. It is critical to look to treatment options like medical nutrition therapy as part of the team approach to health care that can help individuals manage their disease conditions and reduce or eliminate reliance on expensive drug therapies.

Legislation has been introduced in the Senate and House, The Medicare Medical Nutrition Therapy Act (S. 660/H.R. 1187), that will provide for coverage of medical nutrition therapy services by registered dietitians and nutrition professionals under Medicare Part B. The bills have accrued the support of 26 Senators and 208 Representatives. The ADA urges you to provide access to cost effective medical nutrition therapy services that can improve the quality of life for seniors while helping to curb the potential costs of a drug benefit.

Included with this statement is the recently published *Position of The American Dietetic Association: Medical nutrition therapy and pharmacotherapy.* We hope that the Finance Committee will give full consideration to this information as it struggles with the difficult issue of providing Medicare prescription drug coverage.

Thank you.

Attachment: Position of The American Dietetic Association: Medical nutrition therapy and pharmacotherapy

Additional information can be obtained from:

The American Dietetic Association
Division of Government Affairs
1225 Eye Street, NW
Suite 1250
Washington, D.C. 20005
(202)371-0500

Position of The American Dietetic Association: Medical nutrition therapy and pharmacotherapy

ABSTRACT

It is the position of The American Dietetic Association that medical nutrition therapy and lifestyle counseling are integral components of medical treatment for the management of selected conditions for which pharmacotherapy is indicated. The Association promotes a team approach to care for clients receiving pharmacotherapy and encourages active collaboration among dietetics professionals and other members of the health care team. Numerous chronic medical conditions respond to medical nutrition therapy; however, pharmacotherapy may be needed to achieve control. In some cases, medical nutrition therapy and pharmacotherapy may need to be initiated simultaneously. Medical nutrition therapy is critical to the management of a variety of chronic diseases, is effective in managing disease, and is cost-effective. The use of a coordinated multidisciplinary team effort is critical to the success of medical nutrition therapy and pharmacotherapy. Because medical nutrition therapy with pharmacotherapy is a treatment of long duration that requires monitoring of compliance and effectiveness, it is best accomplished through a team approach. *J Am Diet Assoc. 1999;99:227-230.*

Medical nutrition therapy involves the assessment of nutritional status and the assignment of diet, counseling, and/or specialized nutrition therapies to treat an illness or condition (1). Medical nutrition therapy has been integrated into the treatment guidelines for a number of diseases, including cardiovascular disease (2), diabetes mellitus (3), hypertension (4), and obesity (5) based on the efficacy of diet and lifestyle on the treatment of these conditions. Non-adherence with medical nutrition therapy and lifestyle change recommendations may affect a patient's response to medications through interactions of drugs and nutrients. In addition, insufficient adherence with nonpharmacologic interventions may result in more intense pharmacotherapy than would otherwise be required to achieve optimum disease control. The relationship between nonpharmacologic interventions, including medical nutrition therapy, and pharmacotherapy requires a thorough, individualized assessment of potential benefits and risks for each therapeutic option, which is most readily achieved through a coordinated, multidisciplinary team effort.

POSITION STATEMENT

It is the position of The American Dietetic Association that medical nutrition therapy and lifestyle counseling are integral components of medical treatment for the management of selected conditions for which pharmacotherapy is indicated. The Association promotes a team approach to care for clients receiving pharmacotherapy and encourages active collaboration among dietetics professionals and other members of the health care team.

WHEN TO USE MEDICAL NUTRITION THERAPY, PHARMACOTHERAPY, OR BOTH

Many chronic medical conditions are responsive to medical nutrition therapy and other components of lifestyle change, but some conditions may also require pharmacotherapy to achieve optimum control. Risk stratification is a method of ranking the degree of risk for adverse events related to a

medical condition, such as risk of stroke or myocardial infarction in atherosclerotic disease. The level of risk determines the intensity of the intervention. Risk stratification is promoted for conditions such as hypertension, hyperlipidemia, type 2 diabetes mellitus, osteoporosis, and obesity. Medical nutrition therapy and other components of lifestyle change represent the initial intervention when risk stratification indicates that a patient is at relatively low risk of adverse events, or even moderate risk if medication-related adverse effects outweigh the need for rapid control of the disease process. Subsequent steps for those who are not responding adequately to lifestyle change alone, including diet modification and exercise, are characterized by progressively more intense pharmacotherapy based on the number of pharmaceutical agents involved and the potential for serious medication-related adverse effects. Therapy generally advances from an initial lifestyle change, including alterations in nutritional intake, to the addition of a single medication, then to the addition of multiple pharmaceutical agents as required to achieve optimum control. Patients fitting a high-risk profile are generally advised to begin both lifestyle change and pharmacotherapy as the initial intervention, basing the intensity of pharmacotherapy on the degree of risk for adverse events and the rapidity with which control is needed.

Medical nutrition therapy is critical to the management of chronic disease regardless of risk stratification. Medical nutrition therapy and lifestyle counseling are not only effective (6) but also cost-effective (1,7).

POTENTIAL ADVERSE EFFECTS RELATED TO PHARMACOTHERAPY

An estimated 40% of patients who receive medication are expected to experience a therapeutic failure caused by medication-related problems or the development of new medical conditions resulting from the pharmacotherapy (8). Medication-related problems include nonadherence to the medication regimen, as well as adverse events from taking prescribed medications. Nonadherence is estimated to cost $8.5 to $50 billion in direct costs for hospitalization annually (9,10). Another 2 to 3 times this amount is estimated to be spent on indirect costs of nonadherence with medications.

CHRONIC DISEASE AND MEDICAL NUTRITION THERAPY

Patients with chronic disease require long-term management that tends to fall into the purview of the primary care physician and health care team. The characteristics of chronic disease include insidious rather than acute onset, recurring symptoms and of long duration, morbid process with complications, and known pathology and prognosis. Chronic diseases that tend to be modifiable by diet include diabetes mellitus, hypertension, obesity, and cardiovascular disease; therefore, medical nutrition therapy is included in their treatment protocols. Additionally, these diseases are usually treated with pharmacotherapy. Chronic conditions affecting the gastrointestinal tract, such as inflammatory bowel disease and dysmotility syndromes respond to diet modification but frequently require the addition of pharmacotherapy for optimum disease control. Other conditions for which medical nutrition therapy and pharmacotherapy may each offer some aspect of symptom or disease control include Parkinson's disease and seizure disorders responsive to a ketogenic diet. Patients with complex diseases involving organ system dysfunction, such as chronic pulmonary disease, renal disease and immune system diseases, including human immunodeficiency virus/aquired immunodeficiency syndrome, may also benefit from both medical nutrition therapy and pharmacotherapy.

Concurrent medical nutrition therapy and pharmacotherapy usually is of long duration, requires monitoring for compliance and effectiveness, and is best accomplished using a health care team approach. Involvement of nonphysician personnel in providing education, clarification, and reinforcement may improve patient compliance with treatment regimens (11). Encouragement to continue lifestyle modification, including dietary changes, is important even when pharmacotherapy is required to achieve desired disease control. Less intensive pharmacotherapy (eg, lower doses or monotherapy rather than polytherapy) may often be adequate when medical nutrition therapy including lifestyle modification is implemented. For example, patients with obesity and hypertension may be able to achieve desired blood pressure control with weight loss, whereas they achieved inadequate control with pharmacotherapy before weight loss (12). Reduced cost and a lower incidence of side effects are typically associated with less intensive pharmacotherapy. These factors in turn may improve adherence with the overall regimen.

DIABETES MELLITUS AND COMPLICATIONS

Medical nutrition therapy is an essential component of management for type 1 and type 2 diabetes mellitus, although insulin is also required for treatment of type 1 diabetes. Adequate training related to insulin and nutrition management of glucose is crucial to persons with type 1 diabetes mellitus, as tight management of blood glucose has been shown to prevent or delay the progression of retinopathy, microalbuminuria, and neuropathy (13). Tight control includes increasing the number of insulin injections plus monitoring the blood glucose levels and dietary intake more closely compared with conventional control.

Type 2 diabetes mellitus is characterized by an inappropriate response to insulin, often referred to as insulin resistance. Lifestyle modifications, including diet and exercise, are key components of management of the disease. The effect of weight loss on glycemic control is well known (14,15), and diet adjustment to attenuate the rise in blood glucose is an accepted principle of diabetes management (3). When blood glucose levels cannot be adequately controlled by nonpharmacologic methods alone, medications are added. Sulfonylureas, metformin, and acarbose, however, are all associated with side effects that require attention to various aspects of dietary composition or timing (16). Acarbose, in particular, has significant gastrointestinal effects related to blocking of complex carbohydrate by α-glucosidase enzymes. Both side effects and efficacy are linked to the carbohydrate content of the diet (16,17).

OBESITY AND COMPLICATIONS

Obesity is a chronic problem with numerous complications affecting multiple organ systems. Recently released clinical guidelines from the National Heart, Lung, and Blood Institute focus on treatment of obesity, a condition described as the "second leading cause of preventable death in the United States" (18). A number of studies have documented the effectiveness of short-term appetite suppressant therapy (19,20). A recent meta-analysis of diet and exercise studies demonstrated the effectiveness of diet alone and diet plus exercise with reported weight losses at 1 year of 6.6 ± 0.5 and 8.6 ± 0.8 kg, respectively (21). Although therapy with obesity drugs has been shown to aid in weight loss, they should be used only as an adjunct to medical nutrition therapy and exercise (22), and only in obese persons at greatest risk from overweight. Indications for adjunctive use include body mass index of 30 or greater without complications or 27 and greater with compli-

cations (5). Additionally, pharmacotherapy may be beneficial in the maintenance of small yet clinically notable weight losses. Small weight losses of less than 10% of starting body weight appear beneficial for glycemic control, reducing cholesterol levels, and reducing blood pressure (14).

HYPERTENSION

Food selection and intake has a recognized influence on blood pressure (23). Both weight reduction and sodium restriction have been identified as important factors in reducing blood pressure. With nonpharmacologic interventions alone in persons with high-normal diastolic blood pressure, moderate sodium restriction lowered diastolic pressure by 0.9 mm Hg, whereas weight reduction resulted in a 2.3 mm Hg decrease in diastolic pressure (24). Data pooled from several randomized clinical trials also support at least modest diastolic blood pressure reductions (2.6 mm Hg) with moderate sodium restriction in most patients (25). This compares to diastolic blood pressure decreases averaging 12.3 mm Hg for all drug treatments (range=11.5-13.1 mm Hg for individual medications) and 8.6 mm Hg for lifestyle changes including weight loss, dietary sodium reduction, decreased alcohol intake, and increased physical activity (26). Sodium restriction and increased dietary potassium have also been reported to lower the amount of medication required for the treatment of hypertension (27).

Weight loss of approximately 10 kg has also been shown to reduce blood pressure with or without concomitant pharmacotherapy (28) and without sodium restriction (12). These studies support improved blood pressure control with current levels of pharmacotherapy when weight loss occurs.

The Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recognizes the ongoing role of lifestyle modification, including weight reduction and salt restriction, in blood pressure control in an algorithm for selecting hypertensive therapy (4). Step 1 therapy is lifestyle modification alone, and Step 2 (begun after inadequate response at Step 1) is continued lifestyle modification and initial pharmacological selection.

HYPERLIPIDEMIA AND CORNARY HEART DISEASE

The effect of medical nutrition therapy on blood lipids has long been recognized. The Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults recognizes dietary therapy as the first line of therapy, while pharmacotherapy is reserved for patients at high risk for coronary heart disease (CHD) (2). The National Cholesterol Education Program (NCEP) recommendations for nutrient intakes were intended to reduce risk of CHD through lowering blood cholesterol (29). A change from the typical American diet to the NCEP Step 1 recommendations of 30% of energy from fat with less than 10% saturated fat and less than 300 mg cholesterol per day would reduce total cholesterol and low-density lipoprotein cholesterol (LDL-C) by 5%, according to a meta-analysis of 224 dietary intervention studies (30).

Other reports recommend a stepped-care approach to treating high serum cholesterol levels, with the intensity of treatment based on the CHD risk (2). NCEP used LDL-C levels to establish initiation of medical nutrition therapy and/or drug treatment with dietary treatment, initiated at lower levels of LDL-C. The Lifestyle Heart Trial (31) noted a correlation with the degree of change in vessel stenosis and extent of lifestyle change across a broad range, suggesting potential for slowing progression of atherosclerosis with modest changes and potential halting or reversal of coronary atherosclerosis through considerable lifestyle modification.

Current recommendations include aggressive therapy for persons with CHD or at least 2 risk factors for CHD. Medical nutrition therapy is the first step in treatment for dyslipidemia and may facilitate reducing lipid levels. Medications are recommended when nutrition intervention fails to reduce LDL-C levels below 2.37 mmol/L in patients with CHD or below 4.14 mmol/L in patients with 2 or more risk factors (2). The availability of relatively safe, effective, and well-tolerated 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors, or "statins," may improve compliance with medications, but does not eliminate the need for continued nutrition intervention.

THE ROLE OF THE HEALTH CARE TEAM

A multidisciplinary approach is advocated to develop clinical pathways and disease management systems to help reduce variability in care and control costs for chronic multisystem conditions, such as diabetes mellitus and congestive heart failure (32,33). The multidisciplinary team assesses the patient and develops a care plan, taking into consideration the patient's readiness to change behaviors and, thus, ability to adhere to the plan.

Multidisciplinary care requires members in each discipline to have a basic understanding of the condition being treated and an appreciation for the expertise provided by members of the other disciplines involved in patient care. The goal of a health care team is to provide a well-organized method of achieving multidisciplinary care. Team members have some degree of overlapping knowledge, but each brings some area of expertise to patient management. Dietetics professionals, for example, provide expertise related to drug and nutrient interactions, the nutrient content of foods, and the relationship of foods and nutrients to health and disease (34).

Multidisciplinary teams including a dietetics professional have been used for many years in the management of specialized nutrition support. Benefits of such teams have included improved clinical outcomes and cost savings (34). Critical care patients surviving acute respiratory failure and mechanical ventilation have been shown to benefit from the recommendations provided by multidisciplinary health care teams that include registered dietitians. When the recomendations of a team were followed, length of time spent in the intensive care unit and overall length of hospitalization decreased significantly, resulting in an estimated cost reduction of $20,000 per patient per hospital stay (35). Improved quality of life has also been reported as a result of multidisciplinary team management. In a study by Rich et al (36), a group of 282 elderly patients were hospitalized for congestive heart failure. A 90-day trial of multidisciplinary management resulted in decreased costs plus improved quality of life. The nurse-led team included a dietitian, a geriatric cardiologist, and a home care provider.

Multidisciplinary disease management programs aimed at chronic multisystem diseases are anticipated to be better accepted by both patients and providers when all relevant professionals are involved in the development of the program (32). This suggests that for conditions responsive to medical nutrition therapy, dietetics professionals should be involved along the entire continuum of care, from program development through implementation.

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[1]To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. Cholesterol of 5.00 mmol/L=193 mg/dL

CONCLUSIONS

Patients who adhere to medical nutrition therapy and adopt other appropriate components of lifestyle change may prevent or delay the need for pharmacotherapy or allow discontinuation of pharmacotherapy after a period of time, although continuous pharmacotherapy is required in some cases. The management of chronic and complex conditions requires collaborative efforts between health care professionals from multiples disciplines, including dietetics professionals. This multidisciplinary approach can help patients achieve optimum disease control through a combination of medical nutrition therapy, other components of lifestyle change, and pharmacotherapy.

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TESTIMONY FOR THE RECORD

BEFORE THE

UNITED STATES SENATE

COMMITTEE ON FINANCE

HEARING ON MEDICARE PRESCRIPTION DRUG BENEFIT

REPRESENTATIVE BENJAMIN L. CARDIN
REPRESENTATIVE WILLIAM J. COYNE
REPRESENTATIVE SANDER M. LEVIN

WEDNESDAY, JUNE 23, 1999

Chairman Roth and Members of the Senate Finance Committee, we appreciate the opportunity to share our views with you on one of the most pressing problems facing America's older and disabled citizens today–access to comprehensive medical care. Medicare, the federal health insurance program for the elderly and disabled, covers a large number of medical services–inpatient hospitalization care, physician services, physical and occupational therapy, and skilled nursing facility, home health and hospice care are all covered by the Medicare program. Despite Medicare's success in eliminating illness as a potential cause of financial ruin for elderly Americans, senior citizens still spend almost one-third of their income on health care, much of it for costly prescription drugs.

When Congress created Medicare in 1965, prescription drugs were not a standard feature of most private insurance policies. But health care in the United States has evolved considerably in the last 34 years. Now most private health plans cover drugs because they are an essential component of modern health care. They are viewed as integral in the treatment and prevention of diseases. But Medicare, for all its achievements, has not kept pace with America's health care system. It is time for Medicare to modernize.

Many states have tried to fill the gap left by Medicare. Each of our states has a pharmaceutical assistance program which attempts to help the most desperate seniors, but leaves thousands uncovered. Currently, Macomb County, Michigan is working to implement the first county-based prescription drug program in the nation. The Macomb program would help seniors who have no other source of coverage. But the states have not been able to do it all, and their efforts have left gaping holes in the safety net.

Because Medicare does not pay for prescription drugs, its beneficiaries, over 80% of whom use a prescription drug each and every day, must either rely on Medicaid if they qualify, purchase private supplemental coverage, join a Medicare HMO that offers drug benefits, or pay for them from their fixed incomes. These costs can be extraordinarily burdensome for the elderly, who already have the highest out-of-pocket costs of any age group and who take, on average, eighteen prescriptions each year.

Medicaid does provide prescription drug coverage. However, many elderly people are above the federal poverty level but still can't afford their medications. For example, a senior citizen in Pennsylvania with heart disease, high blood pressure, and diabetes, a common disease grouping, would spend $965 a year on medications -

- almost a month and a half's Social Security payments. And nearly 60% of Medicare beneficiaries with incomes below the federal poverty level were not enrolled in Medicaid as recently as 1997. Furthermore, even Medicaid enrollees with drug benefits must forgo some of their medications. In fact, eleven state Medicaid programs have imposed caps on the number of prescriptions covered each month.

The drug coverage available through Medigap leaves much to be desired. Only three of the ten standardized Medigap plans offer drug coverage, and these plans–H, I, and J--have limits on the benefits and high cost sharing. Two plans have caps of $1250, and the third has a cap of $3000. In addition, all three policies require beneficiaries to pay 50% coinsurance for their drugs. The high cost of these Medigap policies puts them out of reach for most low-to-moderate income Medicare enrollees. In Maryland, a 70 year-old beneficiary buying a Medigap policy with drug benefits has to pay between $1100 and $3550 per year.

Some beneficiaries get drug benefits through employer-sponsored retiree plans. Although between 60 and 70 percent of large employers offered retiree health benefits in the 1980s, fewer than 40 percent do so today. Of these employers, nearly one-third do not provide drug benefits to their retirees.

So that leaves Medicare HMOs. Nearly one-quarter of Medicare+Choice enrollees–1.5 million beneficiaries--do not have drug benefits today. Nine of ten plans that do offer drugs impose annual caps, some of which are as low as $600. In fact, some seniors in Medicare HMOs are relying on pharmaceutical samples from their physicians to get sufficient supplies of medications. Twenty-five percent of enrollees with drug coverage pay a monthly premium to join the HMO, and these premiums are certain to rise next year. Last October, four of the eight HMOs offering Medicare coverage in Maryland exited the program, abandoning 34,600 seniors. In all but the metropolitan areas, only one HMO was left, and its monthly premium increased from zero to $75.

Next year, the situation is likely to worsen. The lone carrier in Maryland's sixteen rural counties is seriously considering exiting the market. Unfortunately, this dilemma is not unique to Maryland. In a June 15 letter to Congress, Karen Ignagni, President of the American Association of Health Plans, predicts that "tens of thousands of beneficiaries will have their coverage disrupted because of health plans' forced exits from counties in Arkansas, California, Florida, Idaho, Louisiana, Massachusetts, Missouri, New Jersey, Ohio, Pennsylvania, Virginia, and

Washington." Many of the beneficiaries in those counties who took a leap of faith into Medicare+Choice will have no choice six months from now. They will be returned automatically to Medicare fee-for-service because that will be the only option available to them. To add insult to injury, they will not be guaranteed the ability to join a Medigap plan with drug benefits, because BBA only assures re-entry into plans "A", "B", "C" or "F", none of which includes drugs.

Finally, the benefits offered by Medicare+Choice plans are neither guaranteed nor permanent. Because they are not part of the basic Medicare benefit package, which by law must be included in all Medicare+Choice plans, drug benefits are considered "extra" and as such can change from year to year. This means that even in those counties where plans remain in the Medicare market, there is no certainty that they will continue to offer drug benefits or that they will not severely reduce the dollar limits on that benefit. This has already happened in many areas. The largest HMO in Western Pennsylvania placed a cap of $1,000 a year on prescription drug benefits last year, leaving many sick recipients who had given up Medigap insurance with no place to go. The deadline for HMOs to submit their proposals for the year 2000 to the Health Care Financing Administration is July 1, just eight days from today. HCFA estimates that 16 million seniors, or 40% of all beneficiaries, will lack drug coverage beginning next year.

These statistics combine to make us painfully aware of the gaping hole in Medicare's safety net. This Congress can move this session to patch it before more elderly and disabled citizens fall through. Last month, we joined with two of our colleagues on the Ways and Means Committee to introduce legislation to accomplish this. HR 1796, the Medicare Chronic Disease Prescription Drug Benefit Act, recognizes the importance of preventive care and provides coverage for drugs that have been determined to show progress in treating chronic diseases.

Why *chronic* diseases? Because the average drug expenditures for elderly persons with just one chronic disease are more than twice as high than for those without any. Because of those incredibly high costs, seniors are not taking the medications they need and not controlling their illnesses. Studies by AARP and other groups show that seniors try to "stretch" their medications by skipping days and splitting doses, a strategy any health professional will tell you is ineffective at best and dangerous at worst. We should be making sure seniors properly control their conditions because we know from years of advanced medical research that treating these conditions will reduce costly inpatient hospitalizations and expensive follow-up care.

Furthermore, this bill addresses those beneficiaries who have the greatest need for assistance with purchasing their medications: a review of the Medicare+ Choice program reveals that seniors who join HMOs are younger and healthier than those in fee-for-service Medicare. This tells us that it is the older, sicker seniors, precisely the ones who need prescriptions the most, who have reduced access to drug benefits. State pharmaceutical assistance programs and the programs set up by pharmaceutical companies are also biased in favor of one-time medication needs, not managing chronic illness. For example, Michigan seniors can qualify for 3 months of emergency prescription coverage if they have a household income below $1,356 for a couple and spend at least 10% of their income on medication. While this gives a temporary break to some seniors, it is not enough to meet people's everyday needs.

Our bill addresses their needs. It begins with five chronic diseases–diabetes, hypertension, congestive heart disease, major depression, and rheumatoid arthritis--that have high prevalence among seniors and whose treatment will show improvement in beneficiaries' quality of life and reduce Medicare's overall expenditures.

The Medicare costs associated with inpatient treatment of these diseases are exorbitant. We have attached for the record fact sheets that illustrate the enormous price tags borne by the Medicare Part A Trust Fund when these chronic conditions remain untreated.

The bill we have introduced provides coverage for certain medications after an annual $250 deductible is met, with no copayment for generics and a 20% copayment for brand-name drugs. Qualified Medicare Beneficiaries (QMBs) and Specified Low-Income Medicare Beneficiaries (SLMBs) will be exempt from deductibles and copays. The Agency for Health Care Policy and Research will review available data on the effectiveness of drugs in treating these conditions, and based on AHCPR's review, the Department of Health and Human Services will determine the drugs to be covered. Pharmacy Benefit Managers (PBM) under contract on a regional basis with the Health Care Financing Administration will negotiate with pharmaceutical companies to purchase these drugs and will administer the benefit.

This bill covers five major chronic conditions, but we know that there are others that should be covered as well. The legislation provides a process for the Institute of Medicine to determine the effectiveness of this benefit and the Medicare savings it produces, and to recommend additional diagnoses and medications that should be considered for coverage.

Mr. Chairman, modern medicine has the capability of doing extraordinary things. But no medical breakthrough, no matter how remarkable, can benefit patients if they can't get access to it. This cost-effective, economically sound approach to prescription drug coverage is a matter of common sense: if Medicare beneficiaries can secure the medications they need, they will be able to manage their conditions, and will be much less likely to require extended and costly inpatient care. This legislation is a first step, a major step, toward making this happen. We urge the Senate to consider this approach to providing a solid package of prescription drug benefits, an approach that will modernize Medicare for the 21st century for the millions of Americans who depend on it.

Some facts about the conditions

covered by

HR 1796
The Medicare Chronic Disease Prescription Drug Benefit Act of 1999

Introduced May 13, 1999

by

Rep. Benjamin Cardin (MD)
Rep. William Coyne (PA)
Rep. Sander Levin (MI)
Rep. Pete Stark (CA)
Rep. Karen Thurman (FL)

Diabetes

Type 2 Diabetes results from the body's inability to produce or properly use insulin. The underlying problem is insulin resistance with some degree of insulin deficiency.

Nearly 6.3 million people age 65 and older have diabetes.

With its complications, diabetes is the seventh leading cause of death in the United States.

Diabetes prevalence increases with age.

People with diabetes represent 18% of all nursing home residents.

Diabetes is the leading cause of end-stage renal disease. In 1995, approximately 27,900 people initiated treatment for end stage renal disease because of diabetes.

Seniors with diabetes are twice as likely to be hospitalized for kidney infections as those without diabetes.

People with diabetes are 2 to 4 times more likely to have heart disease, to die of heart disease, and to suffer a stroke as people without diabetes.

Between 60 and 70% of people with diabetes have some form of diabetic nerve damage, which can lead to lower limb amputation. The risk of a leg amputation is 15 to 40 times greater for a person with diabetes.

Medicare inpatient care for amputations:

56,000 admissions
650,000 inpatient hospital days
$700 million in expenditures

Medicare inpatient care for end stage renal disease (ESRD):

12,000 admissions
257,000 inpatient hospital days
$237 million in expenditures

Annual Medicare expenditures to treat diabetics: $28.6 billion

Congestive and Ischemic Heart Disease

Heart disease is the largest single cause of death in the United States.

Congestive heart failure is the leading cause of hospitalizations for the elderly.

Every 29 seconds, an American suffers a heart attack.

More than 2,600 Americans die each day from cardiovascular disease.

Healthy Americans aged 67 to 74 can expect to live another 10 -18 years, but if they develop heart failure, their life expectancy is reduced to 2 -4 years.

In women, heart disease is related to the aging process and menopause, and tends to present a decade later than in men.

Drug treatment can reduce death rates for heart attack survivors by 40%, but only half the people who could benefit by these drugs receive them.

Medicare inpatient care for ischemic heart disease:

518,000 admissions
2.6 million inpatient days
$4.2 billion in expenditures

Medicare inpatient care for congestive heart failure:

725,000 admissions
4 million inpatient days
$3.2 billion in expenditures

Hypertension

Hypertension, or high blood pressure, is the leading cause of preventable illness in the elderly.

38% of Medicare beneficiaries, nearly 15 million people, have been diagnosed with hypertension.

Most hypertensive people have no symptoms.
32% percent of hypertensive people don't know they have it.

Between 1986 and 1996, deaths from hypertension increased by 12%.

Hypertension is a major risk factor for heart disease, heart attack, stroke, and kidney failure.

72% of stroke victims are older than age 65.

Widespread use of blood pressure drugs shows sharp reductions in hypertension and enlargement of the heart's left ventricle.

14.8% of people with hypertension are on no therapy, and 26% are on inadequate therapy.

Medicare inpatient care for hypertension:

32,000 admissions
120,000 inpatient hospital days
$76 million in expenditures

Drug therapy for hypertension costs about $400 a year.
Stroke rehabilitation costs about $15,000.

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Major Depression

One million Medicare beneficiaries suffer from major depression.

Rates of depression are particularly high in nursing homes and other residential care settings.

In the elderly, depression commonly coexists with stroke, Parkinson's disease, heart disease, pulmonary disease, and fractures.

Major risk factor for suicide–80% of all suicides are caused by depression.

From 1980 to 1992, the suicide rate among Medicare beneficiaries increased 9%.

Among men and women aged 80 to 84, the suicide rate increased by 35%.

Adequate treatment for depression can reduce overall health costs by 29%.

Major depression leads to more inpatient hospital utilization than any other diagnosis except heart disease.

Depression is chronic and recurring and it requires long term treatment.

Medicare inpatient care for depression:

320,000 admissions
3.8 million inpatient hospital days
$1.8 billion in expenditures

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Rheumatoid Arthritis

Rheumatoid Arthritis is a painful disease characterized by pain, stiffness, swelling, deformity, loss of function in the joints, and inflammation in other body organs.

More than 1.75 million Medicare beneficiaries have rheumatoid arthritis (RA).

Persons aged 60 and older account for more than 50% of RA patients.

Within ten years of diagnosis, 50% to 90% of RA patients are disabled.

RA leads to joint deformities and disability.

RA increases patients' risk for major joint surgery.

In 1994, approximately 710,000 RA patients received care under the Medicare program at a cost of $4.8 billion.

The annual rate of hospitalization for patients with RA (34%) is nearly twice the hospitalization rate for all Medicare beneficiaries (18.7%).

Medicare inpatient care for RA:

365,000 admissions
2 million inpatient hospital days
$3.5 billion in expenditures

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